JUDGE SULLIVAN

08 CV 6993 (RJS)(DF)

ECF CASE

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ANN MONSUE, as Administratrix of the Estate of CLYDE MONSUE, Deceased,

Plaintiff,

-against-

PFIZER INC., PARKE-DAVIS, a division of Warner-Lambert Company and Warner-Lambert Company LLC, WARNER-LAMBERT COMPANY, WARNER LAMBERT COMPANY LLC, EON LABS, INC., SANDOZ INC. and NOVARTIS PHARMACEUTICALS CORPORATION,

Defendants.

Civil Action No.:

(Removed from:
Supreme Court State of New York,
County of New York
Index #: 08/150129)

NOTICE OF REMOVAL OF DEFENDANTS SANDOZ INC. AND NOVARTIS PHARMACEUTICALS CORPORATION

Defendants Sandoz Inc. and Novartis Pharmaceuticals Corporation (collectively "Sandoz") hereby notice removal of this civil action to the United States District Court for the Southern District of New York from the Supreme Court, State of New York, County of New York. Sandoz notices removal of this case pursuant to 28 U.S.C. § 1441, on the grounds that the allegations against Sandoz and Pfizer Inc., Parke-Davis, Warner-Lambert Company and Warner-Lambert Company LLC (collectively, "the Pfizer defendants") are based almost entirely upon

alleged violations of the federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and its accompanying federal regulations, thereby raising substantial federal questions. Sandoz also notices this removal pursuant to 28 U.S.C. § 1442, on the grounds that this action brings into question the discretionary decision of a federal officer.

I. INTRODUCTION

This case involves claims by Plaintiff that Defendants negligently labeled, marketed, and sold the prescription drugs gabapentin and its brand name equivalent, Neurontin®, "for such 'off-label' uses as the treatment of reflex sympathetic dystrophy (RSD)," a purpose for which they had not received FDA approval. (Compl. ¶ 1.) As to the Pfizer defendants, Plaintiff alleges that the companies engaged in improper off-label promotion and marketing of Neurontin in violation of the FDCA. Plaintiff sets out what she believes to be the legal support for these allegations in the first several paragraphs of her "Statement of the Case," where she recites provisions of the FDCA and its implementing regulations. (*Id.* ¶¶ 138-146.) For example, Plaintiff provides the context for conduct that is barred by federal law: "the FDCA prohibits drug manufacturers themselves from marketing and promoting a drug for a use that the FDA has not approved." (*Id.* ¶ 140 (citing 21 U.S.C. § 331(d)).) Plaintiff then states that if a drug manufacturer "desires to market and promote the drug for new uses in addition to those already approved, the materials on 'off-label' usage must meet certain stringent requirements [pursuant to federal law] . . . ." (*Id.* ¶ 142.) Further, Plaintiff explicitly states that it is the federal regulatory scheme that was designed to protect individuals from the misconduct she alleges in the Complaint:

> The above-described statutory and regulatory system and process is designed to protect the public, including plaintiff's decedent, from the dangers arising from drugs which, although approved for a certain specific condition, disease or purpose, could cause injury and harm if used for an 'off-label' purpose . . . and to protect the public, including plaintiff's decedent, from the dangers arising from deceptive, misleading, and inaccurate advertising, marketing, and promotional materials issued directly or indirectly by the manufacturer to encourage the 'off-label' usage of the drug . . . .

(*Id.* ¶ 143.)

Plaintiff asserts that the Pfizer defendants' promotion and advertising of Neurontin was improper because it violated ***federal law*** in numerous ways, including but not limited to, "illegally promoting the sale and use of Neurontin for [off-label uses] . . . in violation of the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 331, et seq.: [and,] offering and paying illegal remuneration to doctors . . . to induce them to promote and prescribe Neurontin for off-label uses, in violation of the federal Anti-kickback Statute, 42 U.S.C. § 1320a-7b(b) . . . " (*Id.* ¶ 245.)

Paragraph 153 of the Complaint succinctly summarizes the gist of the allegations against the Pfizer defendants and illustrates how Plaintiff's claims are inextricably intertwined with federal law:

> Neurontin is not reasonably safe and effective for the treatment of persons suffering from reflex sympathetic dystrophy (RSD), and is not reasonably safe when consumed in higher dosages than those approved by the FDA, and the Pfizer defendants' conduct of illegally advertising, marketing and promoting Neurontin for this 'off-label' use was unlawful, deceptive and misleading and was violation of the FDCA.

(*Id.* ¶ 153.) Resolution of these claims, therefore, will require the Court to interpret the various provisions of the FDCA and resolve substantial questions of federal law.

Plaintiff's claims against Sandoz likewise raise substantial questions of federal law. These claims hinge on the alleged wrongful promotion of gabapentin, and upon the alleged failure of Sandoz to change the labels accompanying its product to make them different from those of Pfizer, the innovator of the product. (*See* Compl. Counts 6-8.)[1] Plaintiff further claims that Sandoz is liable under various theories for "adopting the statements, studies, labeling and

[1] The Complaint contains 177 numbered paragraphs of factual allegations not included in the distinct causes of action, but only eight paragraphs contain specific factual allegations of wrongdoing against Sandoz. These limited allegations are based almost entirely on the theory

representations of the manufacturer of Neurontin," (Compl. ¶ 276), all of which are comprehensively governed by the FDCA and its accompanying regulations. (*Id.* ¶ 140) ("the FDCA prohibits drug manufacturers themselves from marketing and promoting a drug for a use that the FDA has not approved," citing 21 U.S.C. § 331(d).)

However, the labeling of generic drugs is not subject to the discretion of a generic manufacturer, but is under the absolute and total control of the FDA. Additionally, the FDA is the sole authority to determine whether a manufacturer has met its legal obligations regarding warnings. *See* 21 U.S.C. §§ 337, 372; 21 C.F.R. § 5.35 (2000). Thus, the gravamen of Plaintiff's entire Complaint turns on the construction of federal law and, therefore, this Court has removal jurisdiction to address the federal questions presented. *See* 28 U.S.C. § 1331.

Under 28 U.S.C. § 1442, federal jurisdiction also exists when a plaintiff's claim questions the discretionary decision of a federal officer. The FDA has comprehensive, absolute authority over the manufacture, marketing, labeling, production, prescription, distribution, etc., of generic drugs. Any claim that questions any of these activities inherently questions the discretion of a federal officer. Plaintiff, in pursuing allegations that Sandoz negligently labeled or marketed gabapentin, is essentially attempting to usurp this federal discretion and attack the discretionary functions of the FDA. In addition to challenging the discretionary decisions of a federal officer, Plaintiff's allegations raise labeling concerns under the FDCA.[2]

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that Sandoz is liable because of its "adoption" of statements allegedly made by the Pfizer defendants, rather than on any affirmative wrongful conduct. (*See* Compl. ¶¶ 1, 157-163.)

[2] Under the FDCA, all public statements related to a drug's use or efficacy are considered "labeling" and are under the absolute control of the FDA. 21 C.F.R. 202.1(l)(2) (providing an extensive list of marketing materials defined as "labeling" including all "detailing pieces," "exhibits," "mail pieces," "literature," and "reprints . . . for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer.")

II. PURSUANT TO 28 U.S.C. §1446, REMOVAL IS TIMELY

On or about May 28, 2008, Plaintiff filed her Complaint naming Sandoz Inc. and Novartis Pharmaceuticals Corporation as defendants. The action is captioned *Ann Monsue, as Administratrix of the Estate of Clyde Monsue v. Pfizer Inc., et al.*, Index No. 08/150129, Supreme Court, State of New York, County of New York. A true and correct copy of the Complaint and all "process, pleadings, and orders" that have been served on the removing defendants in the state court action are attached as Exhibit A and are being filed with this Notice as required by 28 U.S.C. § 1446(a).

Sandoz Inc. received service of Plaintiff's Complaint in this action on July 7, 2008 and Novartis Pharmaceuticals Corporation received service on July 11, 2008, and they are filing this Notice of Removal within thirty (30) days after service, as required by 28 U.S.C. §1446(b). Although the consent of the other defendants in this action is not needed for removal under 28 U.S.C. § 1442, Defendant Eon Labs, Inc. has consented to the removal of this action and Defendants Pfizer Inc. and Warner-Lambert Company LLC, formerly known as Warner-Lambert Company, on its own behalf and on behalf of its unincorporated division, Parke-Davis, have consented to the removal of this action on federal question grounds and said consents are filed herewith as Exhibit B.

III. THIS CASE INVOLVES A SUBSTANTIAL FEDERAL QUESTION

Jurisdiction over this action is proper pursuant to 28 U.S.C. § 1441(b), as it presents a federal question. *See* 28 U.S.C. § 1331. Plaintiff's claims are inextricably intertwined with and arise from alleged violations of federal statutes and regulations. In particular, the resolution of Plaintiff's allegations necessarily turns on the construction of federal law, namely whether Sandoz and the Pfizer defendants violated the FDCA and/or FDA's regulations. *See City of Chicago v. Int'l Coll. of Surgeons*, 522 U.S. 156, 164 (1997) (a case may "arise under" federal

law "if a well-pleaded complaint established that its right to relief under state law requires resolution of a substantial question of federal law"). Indeed, it will be impossible to resolve Plaintiff's claims without first resolving these intricate federal issues, including the responsibilities of drug manufacturers under the FDCA. *See Hines v. Cenla Cmty. Action Comm. Inc.*, 474 F.2d 1052, 1056 (5th Cir. 1973) ("A case arises under federal law if rights claimed by one party may be defeated by one construction of the statute and sustained by opposite construction.").

Because Plaintiff's claims rely upon the application of federal law, a federal court is the proper forum for addressing them. *See In re Zyprexa Prods. Liab. Litig.*, 375 F. Supp. 2d 170, 170, 172-73 (E.D.N.Y. 2005) (federal question jurisdiction exists because the "substantial federal funding provisions involved and allegations about the violation of federal law through *improper off-label* use [of a prescription drug] present a core of substantial [federal] issues.") (emphasis added).[3] Here, as in *Zyprexa*, Plaintiff has alleged that Sandoz, as well as the Pfizer defendants, marketed and promoted a prescription drug for off-label uses in violation of the FDCA and FDA regulations. (Compl. ¶¶ 142-144.) Nowhere in the Complaint does Plaintiff disclaim her intent to rely on a violation of federal law to establish liability under her state law claims. Absent any disavowal of such reliance, and in light of Plaintiff's express reliance on federal law, it is evident that the interpretation of federal law is essential to the adjudication of Plaintiff's claims. Accordingly, a substantial federal question exists.

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[3] In *Grable & Sons' Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308 (2005) *reh'g denied*, 545 U.S. 1158 (2005), the Supreme Court corrected interpretations of *Merrell Dow Pharm. v. Thompson*, 478 U.S. 804 (1986), that required a federal cause of action as a condition for finding federal question jurisdiction. *Grable* held that there is not one "'single, precise, all-embracing' test for jurisdiction over federal issues embedded in state-law claims . . . [and that determining whether federal question jurisdiction exists requires] the contextual enquiry." *Grable*, 545 U.S. 314, 318.

Lawsuits alleging similar unfair business practices as in this case and brought on behalf of purchasers of Neurontin, including nationwide classes that purport to include Plaintiff, have been filed in a number of United States District Courts, including those in the Southern District of New York, Western District of Missouri, District of Minnesota, District of Nebraska, and numerous others already assigned or in the process of being assigned, to a multidistrict proceeding in the District of Massachusetts styled, *In re Neurontin Marketing, Sales Practices and Prods. Liab. Litig.*, MDL-1629. Because a case is properly removable if it could have been filed in the first instance in federal court, it is significant that lawsuits grounded upon the same set of facts as those alleged here have, in fact, already been filed in federal courts across the country.

The issue of whether federal question jurisdiction exists over a Neurontin plaintiff's claims purportedly brought under state law has arisen in other cases and is likely to arise in future cases. Indeed, a number of cases already transferred to the Neurontin MDL raise this same jurisdictional question. *See, e.g.*, *Ramsey v. Pfizer Inc.*, No. 2:06-cv-04718-MK (E.D. Pa.); *Tilley v. Pfizer Inc.*, No. 1:06-cv-00513-KAJ (D. Del.); *Blackwell v. Pfizer Inc.*, No. 2:06-CV-2295 (E.D. Pa.); *Eckenrode v. Pfizer Inc.*, No. 3:04-cv-240/MCR/MD (N.D. Fla.); *Johnson v. Pfizer Inc.*, No. 2:05-CV-3688 (E.D. La.); *Craft v. Pfizer Inc.*, No. 2:05-cv-310-FtM-VMC-SPC (M.D. Fla.). As such, the MDL Court is the proper court to decide this question to promote "judicial economy and consistency," which is the purpose of the MDL proceeding. *In re Ivy*, 901 F.2d 7, 9 (2d Cir. 1990) (upholding MDL Panel's rejection of plaintiffs' request that remand motion be decided by transferor court; holding that "[t]he jurisdictional issue in question is easily capable of arising in hundreds or even thousands of cases in district courts throughout the nation," and that "[c]onsistency as well as economy is . . . served" if "the jurisdictional

objections [are] heard and resolved by a single court"). The MDL Court is well positioned to decide an issue likely to arise in other Neurontin cases.

IV. REMOVAL IS PROPER ON THE GROUNDS THAT THE ACTION IS AGAINST AN ENTITY ACTING UNDER THE DIRECTION OF A FEDERAL OFFICER

This case may be removed pursuant to 28 U.S.C. § 1442 because it involves an action against "any officer (or any person acting under that officer) of the United States or of any agency thereof." 28 U.S.C. § 1442(a)(1). To establish removal jurisdiction under section 1442(a)(1), a defendant must (1) show that it is a "person" within the meaning of the statute; (2) establish that it was "acting under" a federal officer, which subsumes the existence of a causal connection between the charged conduct and asserted official authority; and (3) raise a colorable federal defense. *In re Methyl Tertiary Butyl Ether ("MTBE") Prods. Liab. Litig.*, 488 F.3d 112, 124 (2d Cir. 2007); *Mesa v. California*, 489 U.S. 121, 129 (1989); *see also Jamison v. Wiley*, 14 F.3d 222, 237-39 (4th Cir. 1994); *Winters v. Diamond Shamrock Chem. Co.*, 149 F.3d 387 (5th Cir. 1998), *cert denied*, 526 U.S. 1034 (1999). The purpose of this right of removal is to guarantee a federal forum in any case where a federal official, or a person acting under a federal official, is entitled to raise a federal defense arising out of his official duties. *Willingham v. Morgan*, 395 U.S. 402, 407 (1969); *see also Arizona v. Manypenny*, 451 U.S. 232 (1981), *cert. denied*, 459 U.S. 850 (1982). The act of removal permits a trial upon the merits "free from local interests or prejudice" and "enables the defendant to have the validity of his [federal] defense adjudicated, in a federal forum." *Manypenny*, 451 U.S. at 241-42 (internal citations omitted); *see also In re Methyl Tertiary Butyl Ether ("MTBE") Prods. Liab. Litig.*, 341 F. Supp. 2d 351, 359 (S.D.N.Y. 2004) (federal officer removal is intended to protect federal interests by providing federal officials a federal tribunal in which to litigate matters concerning acts committed in their federal capacity).

Sandoz meets the test for federal officer removal. Sandoz is a legal entity acting under the direct, detailed and absolute authority of a federal officer in its manufacture and labeling of gabapentin.[4] The Commissioner of the FDA, or his delegee, the Director of the FDA's Office of Generic Drugs, has absolute control over the nature of the product Sandoz is permitted to manufacture, and also has complete control over the warnings Sandoz is permitted to make and the labeling and marketing Sandoz is permitted to produce. Plaintiff's claims directly challenge Sandoz's actions in labeling and marketing gabapentin, as ordered by the FDA, and thus there is a "causal nexus" between the claims and the decisions and conduct performed under color of a federal office. Finally, as Plaintiff's claims raise strong issues of federal preemption, federal regulatory compliance, regulatory estoppel and immunity, Sandoz has "colorable federal defense[s]." *See Feidt v. Owens Corning*, 153 F.3d 124, 127 (3d Cir. 1998); *Magnin v. Teledyne Cont'l Motors*, 91 F.3d 1424, 1427 (11th Cir. 1996).

A. Sandoz Acted Under the Detailed, Absolute Authority of a Federal Officer, and There is a Direct Causal Nexus Between These Actions and Plaintiff's Claims

Plaintiff alleges that Sandoz, despite its knowledge of the studies, off-label usage, and alleged wrongful promotion activities of the Pfizer Defendants "did not change the label" accompanying gabapentin and further "failed to apply to the FDA to change the label subsequent to receiving approval." (Compl. ¶¶ 162-163.) This allegation ignores the reality that labeling and distribution of gabapentin are strictly governed by the ANDA regulatory scheme of the FDCA. 21 U.S.C. § 355(j); *see also* 21 C.F.R. § 314.150.

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[4] Sandoz is a legal "person" for the purposes of removal under 28 U.S.C. § 1442. *See In re MTBE Prods. Liab. Litig.*, 488 F.3d at 124 ("it is clear that corporations are 'persons' within the meaning of the [federal officer removal] statute").

In contrast to the regulatory scheme governing the marketing of innovator drugs, under which manufacturers have some discretion regarding products, labeling and warnings, generic drug manufacturers such as Sandoz are subject to detailed, absolute regulatory and legal requirements that leave them with no discretion to alter or change a product, or to give warnings that are different in any way from those mandated by the FDA Commissioner or his delegee.[5] *See Abbreviated New Drug Applications Regulations,* 57 Fed. Reg. 17,950, 17,957, 17,961 (Apr. 28, 1992). Rather, a generic manufacturer can only alter its labeling when directed by the FDA.[6]

The ANDA process begins with a requirement that the information not be new or innovative, but wholly derivative of information already provided by the innovator manufacturer. *See* 21 U.S.C. § 321(aa) (ANDA must "rel[y] on the approved application of another drug with the same active ingredient to establish safety and efficacy"); 21 U.S.C. § 355(j); 21 C.F.R.

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[5] Plaintiffs allege that "[p]ursuant to 21 C.F.R. § 314.70, manufacturers, such as [Sandoz], who have received approval for a generic drug pursuant to the ANDA process, are allowed to amend a drug's labeling without receiving FDA prior approval . . . [and] may apply to the FDA for approval to amend a drug's labeling . . . to strengthen a contradication [sic], warning, precaution, etc." (Compl. ¶ 161.) However, this interpretation is simply and flatly wrong. Generic manufacturers have *no discretion whatsoever* to alter the labeling of the generic drugs they produce. The most a generic drug manufacturer can do is suggest a labeling change to the FDA, which then will determine whether the change is warranted, and if so, require that both the innovator drug labeling and the generic drug labeling be revised in an identical manner. *See* 57 Fed. Reg. at 17,961; *see also* FDA Guidance for Industry: Revising ANDA Labeling after the Revision of the RLD Labeling, May 2000; FDA Guidance for Industry: Changes to an Approved NDA or ANDA, April 2004, Revision 1; FDA Guidance for Industry: Changes to an Approved NDA or ANDA, November 1999, at 24. Regardless, no generic manufacturer can make a change without being ordered to do so by the FDA. Further, given their unique posture under the FDCA's ANDA process, generic manufacturers have no duty to seek changes in the labeling that they do not have the expertise to evaluate. (*See* Compl. ¶ 162.)

[6] For example, in a December 24, 1996 letter, the FDA cautioned ANDA holders that they cannot adopt innovator labeling that has been unilaterally revised by the innovator unless and until the FDA has approved such revised innovator labeling. The FDA letter stated that "[t]he FDA must still review, possibly recommend changes and approve the [revised innovator drug] labeling before it is acceptable for use as model labeling for an [ANDA] product." Letter from Douglas L. Sporn, Director, Office of Generic Drugs, Center for Drug Evaluation and Review, at 8, attached as Exhibit C.

§ 314.92(a)(1) (FDA-approved conditions of use, active ingredient, route of administration, dosage form, strength, therapeutic effect, and labeling (including all warnings) for gabapentin are mandated by the FDA to be identical to the innovator product).

To underscore the mandatory nature of the ANDA process, the FDA's regulations state that it will not approve an ANDA if "information submitted in the application is insufficient to show that the labeling proposed for the [generic] drug is the *same as* the labeling approved for the listed drug [except] for changes required because of differences approved under a [§ 505(j)(2)(C) suitability] petition . . . or because the [generic] drug and the listed drug are produced or distributed by different manufacturers." 21 U.S.C. § 355(j)(4)(G) (emphasis added); *see also* 21 C.F.R. § 314.127(a)(7); 21 C.F.R. § 314.94(a)(8)(iv) (the FDA requires that an ANDA include "side-by-side comparison of the applicant's proposed labeling . . . with the approved labeling for the reference listed drug with all differences annotated and explained.") In fact, if a generic manufacturer fails to copy the approved innovator labeling, the FDA can remove the generic applicant's marketing authority. 21 C.F.R. § 314.150(b)(10). Finally, a generic drug manufacturer cannot add to or revise any warnings on its product's labeling without the FDA's express prior approval. *See* 57 Fed. Reg. at 17,957, 17,961.

These facts show that Sandoz, as a manufacturer of gabapentin, was at all times acting ultimately under the direct and detailed authority and control of an officer of the United States. The Director of the Office of Generic Drugs is responsible for the approval, manufacturing, and distribution for all generic drugs, including gabapentin. *See* 21 C.F.R. §§ 5.10, 5.103, 5.106 (2004); *see also Winters,* 149 F.3d at 398-401. Plaintiff's claims are a direct attack on a discretionary decision of the FDA because the drug's labels are under the absolute control of its officers. As the *Fung* Court pointed out, "[t]his control requirement can be satisfied by strong

government intervention and the threat that a defendant will be sued in state court 'based upon actions taken pursuant to federal direction.'" *Fung v. Abex Corp.*, 816 F. Supp. 569, 572 (N.D. Cal. 1992) (*citing Gulati v. Zuckerman*, 723 F. Supp. 353, 358 (E.D. Pa. 1989). That is the exact situation of Sandoz in this litigation.

Plaintiff's counsel realizes a generic manufacturer has no discretion to alter the labels that accompany these drugs, but rather this is the FDA's responsibility. Indeed, on May 17, 2004, he filed an FDA Citizens Petition, seeking to have a "black box" warning about suicide added to Neurontin's labeling. He also requested that Neurontin manufacturers be ordered to prepare "Dear Doctor" letters for prescribing physicians to watch for increased depression in patients taking Neurontin. *See* Citizens Petition, attached as Exhibit D.

Thereafter, in multiple letters to Dr. Russell Katz, Director of the Neuropharmacological Drug section of the FDA, Plaintiff's counsel raised issues regarding Neurontin labeling, accusing the FDA of "ineffective oversight" and causing an "imminent health crisis." *See* Letter from Andrew G. Finkelstein to Dr. Katz, dated October 14, 2005, attached as Exhibit E; *see also* Letter from Andrew G. Finkelstein to Dr. Katz, dated March 21, 2005, attached as Exhibit F ("FDA has taken no affirmative action to require Parke-Davis to advise physicians or their patients of the risks of suicide associated with Neurontin . . . [and] never required a stronger warning label be affixed on Neurontin prescriptions . . . The governmental body charged with the responsibility of protecting the health and safety of Americans has done absolutely nothing to prevent entirely preventable deaths.") These FDA requests implicitly acknowledge that it is the FDA's discretion that is at issue with regard to the final labeling of prescription drugs, and not the manufacturer – the FDA has the power and absolute authority to determine what is and what is not included in the labels.

In simplest terms, Plaintiff claims Sandoz was negligent for not taking regulatory actions that the FDA, in its discretion, has already considered and decided not to take. The FDA has made very clear that its comprehensive regulations are the "final word" on drug labeling and warning. *Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products*, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006). Under these FDA rules, a generic manufacturer cannot unilaterally change warnings contained in an approved label, and only the FDA can determine whether labeling revisions are necessary. *Id.*

In *Colacicco v. Apotex, Inc.*, 521 F.3d 253, 276 (3d Cir. 2008), the court affirmed the district court's dismissal of plaintiffs' state-law failure to warn claims under the doctrine of federal preemption. In its decision, the court noted the FDA's statement that "generic drug manufacturers may not add new warnings to the approved labeling for the listed drug." *Id.* at 260 n.5 (citing 57 Fed. Reg. 17,950, 17,953, 17,955, 17,961 (Apr. 28, 1992)). The district court also stated that "principles of deference do not allow us to question the FDA's interpretation of its own regulations--e.g. that generic drug manufacturers can not make changes without prior approval." *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 528 (E.D. Pa. 2006), *aff'd*, 521 F.3d 253, 276 (3d Cir. 2008). Thus, Sandoz has absolutely no authority to provide labeling or warnings outside the FDA approval process. *See* 71 Fed. Reg. at 3935 (the "FDA interprets the [FDCA] to establish both a 'floor' and a 'ceiling,' such that additional disclosures of risk information can expose a manufacturer to liability under the [A]ct").

As Sandoz was acting within the scope of its federally-mandated requirements, under the direct and detailed federal regulation, removal is appropriate. *See Gurda Farms, Inc. v. Monroe County Legal Assistance Corp.*, 358 F. Supp. 841, 844 (S.D.N.Y. 1973) (federal officer removal appropriate when a defendant is governed by "exceedingly complex regulations, guidelines, and

evaluation schemes"); *Green v. Aetna U.S. Healthcare, Inc.*, No. C-00-1292 VRW, 2000 WL 1229226, at *1 (N.D. Cal. Aug. 18, 2000); *Magnin*, 91 F.3d at 1428.

This situation is similar to that in *Winters*, a product liability case against a manufacturer of Vietnam-era defoliant Agent Orange in which the Fifth Circuit affirmed that the claims against the manufacturer were subject to removal under 28 U.S.C. § 1442(a). In reaching that decision, the Fifth Circuit raised a standard that is entirely relevant here: "whether the government specified the composition of Agent Orange so as to supply the causal nexus between the federal officer's directions and the plaintiff's claims." *Winters*, 149 F.3d at 398. The *Winters* Court ultimately found that the manufacturing defendants acted at the direction of a federal officer because the government dictated the specific composition of the Agent Orange, controlled the manner in which the defendants labeled and shipped the product, and maintained ongoing supervision of the product's manufacture, packaging, and delivery. *Id.* at 399-400. The court also found that the plaintiff's claims were directly related to actions taken under color of federal authority. *Id.* at 400-01 (citing 50 U.S.C. App. § 2061 *et seq.* (1988)).

The Fifth Circuit's analysis in *Winters* was followed by Judge Weinstein in his decision in the Agent Orange litigation. *See In re Agent Orange Prods. Liab. Litig.*, MDL No. 381, No. 98-CV-6383, Memorandum & Order (Removal), 11, 13 (E.D.N.Y. Feb. 12, 2004) (opinion attached as Exhibit G) (finding defendant acted under color of federal office because "the method of warning and application was completely in the government's hands," and the government "designed, controlled and supervised production of herbicide Agent Orange").

Sandoz also meets the requirement of a "causal nexus" between Plaintiff's claims and Sandoz's conduct as mandated by FDA officers. Plaintiff attacks the design, the labeling and warnings, and marketing of Sandoz's gabapentin. Sandoz could not make any claims that

differed from what was mandated by the FDA, nor could it decline to give *exactly* the warnings mandated by the FDA. Rather, its actions reflected absolute federal mandates. Plaintiff's claims do not attack Sandoz's decision to meet its federal responsibilities, but rather the FDA's decision to impose these requirements on generic manufacturers.

B. Sandoz Has Federal Defenses to Plaintiff's State Tort Claims

Given Sandoz's showing that its actions regarding gabapentin took place under detailed federal direction and have a "causal nexus," and indeed an inextricable connection with Plaintiff's claims, it only remains for Sandoz to show that it has a colorable federal defense. *Owens Corning*, 153 F.3d at 127; *Magnin*, 91 F.3d at 1427; *Holton v. BCBS of South Carolina*, 56 F. Supp. 2d 1347, 1351 (M.D. Ala. 1999). The federal defense "need only be plausible; its ultimate validity is not to be determined at the time of removal," *Magnin*, 91 F.3d at 1427, as "[a]ny determination as to the merits is collateral to the jurisdictional question," *Holton*, 56 F. Supp. 2d at 1351 (quotations and citations omitted).

Here, Sandoz's federal defenses are far more than plausible, as Plaintiff's state tort claims directly challenge the safety of gabapentin, the adequacy of its labeling and the way in which the FDA monitored its marketing. All of these complaints address discretionary decisions of federal officers under the FDCA.

First, Sandoz has a strong federal defense of preemption of Plaintiff's tort law claims for injuries arising from Plaintiff's decedent's purchase and consumption of gabapentin. These tort claims directly conflict with the extensive and detailed federal regulatory scheme for generic drugs, as it would be impossible for Sandoz to comply with both the duties and obligations therein and the duties Plaintiff seeks to impose. *See Colacicco*, 521 F.3d at 276 (affirming finding that plaintiffs' state-law failure to warn claims were impliedly preempted by the FDCA, court granted defendant manufacturers' motions to dismiss such claims, citing the FDA's amicus

statement that "'a generic drug manufacturer is not permitted to add a warning or caution to the label without *prior* approval from the FDA.'" (emphasis added)); *Dowhal v. SmithKline Beecham Consumer Healthcare,* 88 P.3d 1, 3 (2004) (state law requirement regarding labeling of nicotine patches preempted by FDA labeling requirements); *Carlin v. Superior Ct.*, 920 P.2d 1347, 1353-54 (1996) (pharmaceutical manufacturer may not be held liable for failing to give a warning that it has been expressly precluded by the FDA from giving); *Feldman v. Lederle Labs.*, 592 A.2d 1176, 1185 (1991), *cert. denied,* 50 U.S. 1219 (1992) ("[c]onflict preemption occurs when 'compliance with both federal and state regulations is . . . impossibl[e]' or when state law 'stands as an obstacle to the . . . execution of the full . . . objectives of Congress.'" (internal citations omitted)). Plaintiff's claims necessarily challenge the adequacy of the labels provided and Sandoz's actions in regard to any potential alteration of such labels, which are wholly dictated by the ANDA regulatory scheme of the FDCA, and thus are preempted. *See, e.g., Taylor AG Indus. v. Pure-Gro*, 54 F.3d 555, 561 (9th Cir. 1995) (quoting *Papas v. Upjohn Co.*, 985 F.2d 516, 518 (11th Cir. 1993) (federal regulation of pesticides preempts state failure to warn claims). As a generic manufacturer, Sandoz had *no* latitude to alter or augment the mandated warnings on gabapentin unless commanded to do so by the FDA, or unless the FDA first affirmatively approves changes for the labeling of the "name brand" (as opposed to the generic) drug product. 57 Fed. Reg. at 17,961 (FDA rejects proposition that generic drug producers are permitted to add warnings to their product labeling); *see also* FDA's Guidance for Industry -- Revising ANDA Labeling after the Revision of the RLD Labeling, May 2000.

Sandoz also has other colorable federal defenses to this action. For example, Sandoz asserts a regulatory compliance/regulatory estoppel defense through its compliance with the federal statutory and regulatory scheme under the ANDA system of the federal FDCA. *See, e.g.,*

Dated: August 5, 2008

Respectfully Submitted,

McKENNA LONG & ALDRIDGE LLP

By: _____

Charles E. Dorkey III (CD-8422)
Timothy J. Plunkett (TP-6060)
230 Park Avenue
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Washington, DC 20006
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(202) 496-7756 (facsimile)

Attorneys for Defendants Sandoz Inc. and Novartis Pharmaceuticals Corporation

EXHIBIT A

CORPORATION SERVICE COMPANY®

BZT / ALL
Transmittal Number: 5899793
Date Processed: 07/12/2008

Notice of Service of Process

Primary Contact: Mr. Eric Pomerantz
Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Entity:	Sandoz Inc. Entity ID Number 0231103
Entity Served:	Sandoz Inc.
Title of Action:	Ann Monsue, as Administratrix of the Estate of Clyde Monsue vs. Pfizer, Inc.
Document(s) Type:	Summons/Complaint
Nature of Action:	Product Liability
Court:	Supreme Court New York, New York
Case Number:	150129/2008
Jurisdiction Served:	New York
Date Served on CSC:	07/11/2008
Answer or Appearance Due:	30 Days
Originally Served On:	New York Department of Corporations 07/07/2008
How Served:	Certified Mail
Plaintiff's Attorney:	Andrew G. Finkelstein 845-562-0203

Information contained on this transmittal form is for record keeping, notification and forwarding the attached document(s). It does not constitute a legal opinion. The recipient is responsible for interpreting the documents and taking appropriate action.

To avoid potential delay, please do not send your response to CSC

CSC is SAS70 Type II certified for its Litigation Management System.

2711 Centerville Road Wilmington, DE 19808 (888) 690-2882 | sop@cscinfo.com

RECEIVED
JUL 15 2008
LEGAL DEPARTMENT
SANDOZ INC.

State of New York - Department of State
Division of Corporations

Party Served:
SANDOZ INC.

Plaintiff/Petitioner:
MONSUE, ANN

CORPORATION SERVICE COMPANY
80 STATE STREET
ALBANY, NY 12207-2543

Dear Sir/Madam:
Enclosed herewith is a legal document which was served upon the Secretary of State on 07/07/2008 pursuant to SECTION 306 OF THE BUSINESS CORPORATION LAW. This copy is being transmitted pursuant to such statute to the address provided for such purpose.

Very truly yours,
Division of Corporations

State of New York - Department of State
Division of Corporations

Party Served:
NOVARTIS PHARMACEUTICALS CORPORATION

Plaintiff/Petitioner:
MONSUE, ANN

NOVARTIS PHARMACEUTICALS CORPORATION
59 ROUTE 10
EAST HANOVER, NJ 07936

Dear Sir/Madam:
Enclosed herewith is a legal document which was served upon the Secretary of State on 07/11/2008 pursuant to SECTION 306 OF THE BUSINESS CORPORATION LAW. This copy is being transmitted pursuant to such statute to the address provided for such purpose.

Very truly yours,
Division of Corporations

FILE #248524-06/rag

DATE OF FILING: 5/28/08
INDEX #: 150129/2008

Plaintiff designates
New York County
as the place of trial.

The basis of venue is:
Principal place of
business of Defendant:
PFIZER INC.

Plaintiff reside at:
County of Dickson
State of Tennessee.

SUPREME COURT STATE OF NEW YORK
COUNTY OF NEW YORK

RECEIVED
JUL 18 2008

ANN MONSUE, as Administratrix of the Estate of
CLYDE MONSUE, Deceased,

Plaintiff(s),

-against-

SUMMONS

PFIZER INC., PARKE-DAVIS, a division of Warner-Lambert
Company and Warner-Lambert Company LLC,
WARNER-LAMBERT COMPANY,
WARNER-LAMBERT COMPANY LLC,
EON LABS, INC., SANDOZ INC. and
NOVARTIS PHARMACEUTICALS CORPORATION,

Defendant(s).

To the above named defendant(s):

YOU ARE HEREBY SUMMONED to answer the complaint in this action and to serve a copy of your answer, or, if the complaint is not served with this summons, to serve a notice of appearance, on the Plaintiff's Attorney(s) within -20- days after the service of this summons, exclusive of the day of service (or within 30 days after the service is complete if this summons is not personally delivered to you within the State of New York); and in case of your failure to appear or answer, judgment will be taken against you by default for the relief demanded in the complaint.

FINKELSTEIN & PARTNERS, LLP
Attorneys for Plaintiff(s)
436 Robinson Avenue
Newburgh, New York 12550
1-845-562-0203

ANDREW G. FINKELSTEIN, ESQ.

Dated: May 27 . 2008.
DEFENDANT'S ADDRESS:
SEE VERIFIED COMPLAINT

eFile@courts.state.ny.us
05/28/2008 02:35 PM

To epolimeni@lawampm.com
cc
bcc
Subject NYSCEF: New York - Tort <COMPLAINT> (Ann Monsue et al vs Pfizer Inc. et al) Confirmation Of EFiling

This is an AUTOMATED response

The NYS EFiling web site has received documents from the User, ELEANOR L POLIMENI, for the case/claim with the caption

Ann Monsue et al vs Pfizer Inc. et al

Email Notifications Sent to:
epolimeni@lawampm.com

You can view the contents of the submitted documents by clicking on the hyperlinks that appear in the body of this message below.

The documents received are initial papers for an EFiling case/claim. Under the EFiling Rules for Supreme Court cases (Uniform Rule 202.5-b(e)(4)), such papers are filed when received by the EFiling site accompanied by the required payment information. If the filer selects the "Pay at the County Clerk?s Office" option, the papers will be in pending status until payment is submitted. You will be notified via e-mail as soon as a claim/index number is assignedto this case/claim.
Document Links ...

COMPLAINT
https://iapps.courts.state.ny.us/fbem/DocumentDisplayServlet?documentId=+DfYoM/1JweVtVKo27064Q==&system=prod

SUMMONS
https://iapps.courts.state.ny.us/fbem/DocumentDisplayServlet?documentId=+DfYoM/1JwfhkFfKC59hpw==&system=prod

If the hyperlink does not display the document by clicking on it, cut and paste the entire document link into your browser.

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

----------x

IN RE:
NEURONTIN PRODUCT LIABILITY LITIGATION

Index No. 765000/05

----------x

DEFENDANT'S CONSENT TO ELECTRONIC FILING

[Plaintiff(s) name]

-against-

Index No. _____/20 ____

[Defendant(s) name]

----------x

Pursuant to Case Management Order No. 7 ("CMO No. 7"), I, _____, am a New Defendant (as that term is defined in Section II. Paragraph 5. of CMO No. 7) or an attorney for a New Defendant. I consent to the use of electronic filing in the individual case listed above and in the Master Case, Index No. 765,000/05 first listed above, including with regard to service of interlocutory papers as provided in CMO No. 7, and I provide the following e-mail addresses for the purposes of service (the Primary Address) and giving additional notice of each filing pursuant to the terms set forth in CMO No. 7:

1. _____ (Primary Address)

2. _____

3. _____

As required under CMO No. 7, I attest that I filed this Defendant's Consent to Electronic Filing within 30 days of service.

_____
Signature

_____
Print or Type Name

Attorney for _____

_____ (Firm Name)

_____ (Firm Address)

_____ (Phone)

_____ (E-mail Address)

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

----------x

IN RE:
NEURONTIN PRODUCT LIABILITY LITIGATION

Index No. 765,000/05

----------x

NOTICE OF AVAILABILITY OF ELECTRONIC FILING

[Plaintiff(s) name]

-against-

Index No. _____/20 ___

[Defendant(s) name]

----------x

PLEASE TAKE NOTICE that Plaintiffs and Defendants Pfizer Inc. and Warner-Lambert Company LLC, formerly known as Warner-Lambert Company, on its own behalf and on behalf of its unincorporated division, Parke-Davis, Teva Pharmaceuticals USA, Inc., Ivax Pharmaceuticals, Inc., Rite Aid Corporation, Wegmans Food Markets Inc. and Wegmans Food Pharmacy (hereinafter "Defendants") in the above-captioned action consent and intend that this action proceed as an electronically-filed case pursuant to the terms set forth in Case Management Order No. 7 ("CMO No. 7"). Service of papers by electronic means cannot be made upon a party unless that party consents to use of the system.

Under CMO No. 7, each New Defendant (defined as any defendant other than those parties described by the term "Defendants," above) shall have 30 days from the date of service either to consent or to decline to participate in the Court's electronic filing system. Each New Defendant that consents shall file a Defendant's Consent to Electronic Filing form, which is provided herewith.

General Information

In New York state court practice, certain actions may be commenced and processed by means of the electronic filing system, including tort claims and commercial claims in the Supreme Court in New York County and other designated Counties.

Electronic filing offers significant benefits for attorneys and litigants, permitting papers to be filed with the Court and served in a simple, convenient, and expeditious manner. Electronically filed case documents are filed with the court by filing on the Court website, which can be accessed at any time, day or night, at www.nycourts.gov/efile. In this litigation, electronic filing is governed by Case Management Order No. 7, and, where applicable, Section 202.5-b of the Uniform Rules for the Trial Courts. A copy of Case Management Order No. 7 is attached hereto.

Instructions

1. New Defendants are strongly encouraged to consent to electronic filing.

2. Pursuant to CMO No. 7, you have 30 days from the date of service either to consent or to decline to participate in electronic filing. To consent, you must file a Defendant's Consent to Electronic Filing form, which is provided herewith. Please transmit the consent form (copied to other counsel) to the Electronic Filing Resource Center, Room 119, 60 Centre Street, New York, New York 10007. If you are already a registered Filing User of the system, you can consent on-line in the case.

3. Pursuant to CMO No. 7, you have ten days from the date of filing of a Defendant's Consent to Electronic Filing form to register for electronic filing by completing and signing a registration form and contacting the Electronic Filing Resource Center at

efile@courts.state.ny.us or 646-386-3033. The registration form is available on the e-filing website listed above.

4. For additional information about electronic filing, see the *User's Manual* and *Frequently Asked Questions* on the Court website or contact the Resource Center.

Dated: _____, 2008

_____ (Name)

_____ (Firm)

_____ (Address)

_____

_____ (Phone)

_____ (Fax)

_____ (E-mail)

Attorney(s) for

20080709

FILE #348524-06/rag

DATE OF FILING: 5/28/08
INDEX #: 150129/2008

Plaintiff designates
New York County
as the place of trial.

The basis of venue is:
Principal place of
business of Defendant:
PFIZER INC.

Plaintiff reside at:
County of Dickson
State of Tennessee.

SUPREME COURT STATE OF NEW YORK
COUNTY OF NEW YORK

----------X

ANN MONSUE, as Administratrix of the Estate of
CLYDE MONSUE, Deceased,

Plaintiff(s),

-against-

SUMMONS

PFIZER INC., PARKE-DAVIS, a division of Warner-Lambert
Company and Warner-Lambert Company LLC,
WARNER-LAMBERT COMPANY;
WARNER-LAMBERT COMPANY LLC,
EON LABS, INC., SANDOZ INC. and
NOVARTIS PHARMACEUTICALS CORPORATION,

Defendant(s).

----------X

To the above named defendant(s):

YOU ARE HEREBY SUMMONED to answer the complaint in this action and to serve a copy of your answer, or, if the complaint is not served with this summons, to serve a notice of appearance, on the Plaintiff's Attorney(s) within -20- days after the service of this summons, exclusive of the day of service (or within 30 days after the service is complete if this summons is not personally delivered to you within the State of New York); and in case of your failure to appear or answer, judgment will be taken against you by default for the relief demanded in the complaint.

FINKELSTEIN & PARTNERS, LLP
Attorneys for Plaintiff(s)
436 Robinson Avenue
Newburgh, New York 12550
1-845-562-0203

ANDREW G. FINKELSTEIN, ESQ.

Dated: May 27, 2008.
DEFENDANT'S ADDRESS:
SEE VERIFIED COMPLAINT

F&P File #248524-06/rag

STATE OF NEW YORK
SUPREME COURT : COUNTY OF NEW YORK

----------x

ANN MONSUE, as Administratrix of the Estate of CLYDE MONSUE, Deceased,

Plaintiff,

-against-

VERIFIED COMPLAINT

PFIZER INC., PARKE-DAVIS, a division of Warner-Lambert Company and Warner-Lambert Company LLC, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY LLC, EON LABS, INC., SANDOZ INC. and NOVARTIS PHARMACEUTICALS CORPORATION,

Defendants.

----------x

Plaintiff, by attorneys, FINKELSTEIN & PARTNERS, LLP, THE LANIER LAW FIRM, P.L.L.C., and BROWN & CROUPPEN, P.C., as and for the Verified Complaint herein allege upon information and belief the following:

STATEMENT OF THE CASE

1. This is an action to recover damages for personal injuries sustained by, and the wrongful death of plaintiff's decedent, CLYDE MONSUE, as the direct and proximate result of defendants' wrongful conduct in connection with the designing, developing, manufacturing, distributing, labeling, advertising, marketing, promoting, and selling of the prescription drug Neurontin, which was marketed and sold by the defendants, PFIZER INC., PARKE-DAVIS, a Division of Warner-Lambert Company and Warner-Lambert Company LLC. (hereinafter referred to as "PARKE-DAVIS"), WARNER-LAMBERT COMPANY and WARNER-

LAMBERT COMPANY LLC, (hereinafter collectively referred to as the "Pfizer defendants"), and the prescription drug gabapentin, the generic form of Neurontin, which was manufactured, marketed and sold by the defendants, EON LABS, INC., SANDOZ INC. and NOVARTIS PHARMACEUTICALS CORPORATION (hereinafter referred to as the "Eon defendants"), especially for such "off-label" uses as the treatment of reflex sympathetic dystrophy (RSD), even though Neurontin and gabapentin had not received FDA approval for such use, and at dosages higher than had been approved by the FDA and had been properly tested on humans, even though the drug had not been tested and studied for such use and had not been found to be safe and effective at any dosage for the reflex sympathetic dystrophy (RSD).

PARTIES AND JURISDICTION

2. That the above-named plaintiff's decedent, CLYDE MONSUE, was the husband Next of Kin and Personal Representative of above-named, ANN MONSUE. and on and prior to May 29, 2007, the Deceased and Personal Representative resided in Dickson County, State of Tennessee.

3. That prior to the commencement of this action by Order of the Probatet Court of Dickson County, State of Tennessee, the plaintiff, ANN MONSUE, was appointed Personal Representative of the Estate of the deceased, CLYDE MONSUE, on the 21st day of May, 2008, and at all times hereinafter mentioned, duly qualified and entered upon her duties as such Personal Representative and is now acting in such capacity. A copy of said Order is attached hereto.

4. That at the time of death on May 29, 2007, plaintiff's decedent was then of the age of 64 years and prior thereto, was generally in good health, industrious and possessed all faculties.

5. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., was and still is a foreign corporation organized under the laws of the State of Delaware with its principal place of business at 235 E. 42nd Street, New York, N.Y. 10017.

6. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., was and still is a foreign corporation authorized to do business in the State of New York.

7. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., was and still is a business entity actually doing business in the State of New York.

8. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, a division of Warner-Lambert Company and Warner-Lambert Company LLC (hereinafter "PARKE-DAVIS"), was and still is a foreign corporation organized under the laws of the State of Michigan.

9. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, was and still is a foreign corporation authorized to do business in the State of New York.

10. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, was and still is a business entity actually doing business in the State of New York.

11. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY was and still is a foreign corporation organized under the laws of the State of Delaware.

12. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, was and still is a foreign corporation authorized to do business in the State of New York with its principal place of business at 235 E. 42nd Street, New York, N.Y. 10017.

13. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, was and still is a business entity actually doing business in the State of New York.

14. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, is a division of the defendant, WARNER-LAMBERT COMPANY.

15. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, is a subsidiary of the defendant, WARNER-LAMBERT COMPANY.

16. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, was and still is a foreign limited liability company organized under the laws of the State of Delaware.

17. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, was and still is a foreign limited liability company authorized to do business in the State of New York.

18. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, was and still is a business entity actually doing business in the State of New York.

19. That at all times hereinafter mentioned, upon information and belief, the defendant, EON LABS, INC., was and still is a foreign corporation organized under the laws of

the State of Delaware with its principal place of business at 227-15 North Conduit Avenue, Laurelton, NY 11413.

20. That at all times hereinafter mentioned, upon information and belief, the defendant, EON LABS, INC., was and still is a foreign corporation authorized to do business in the State of New York.

21. That at all times hereinafter mentioned, upon information and belief, the defendant, EON LABS, INC., was and still is a business entity actually doing business in the State of New York.

22. That at all times hereinafter mentioned, upon information and belief, the defendant, SANDOZ INC., was and still is a foreign corporation organized under the laws of the State of Colorado with its principal place of business at 506 Carnegie Center Boulevard, Ste. 400, Princeton, NJ 08540.

23. That at all times hereinafter mentioned, upon information and belief, the defendant, SANDOZ INC., was and still is a foreign corporation authorized to do business in the State of New York.

24. That at all times hereinafter mentioned, upon information and belief, the defendant, SANDOZ INC., was and still is a business entity actually doing business in the State of New York.

25. That at all times hereinafter mentioned, upon information and belief, the defendant, NOVARTIS PHARMACEUTICALS CORPORATION, was and still is a foreign corporation organized under the laws of the State of Delaware with its principal place of business at 59 Route 10, East Hanover, New Jersey 07937

26. That at all times hereinafter mentioned, upon information and belief, the defendant, NOVARTIS PHARMACEUTICALS CORPORATION was and still is a foreign corporation authorized to do business in the State of New York.

27. That at all times hereinafter mentioned, upon information and belief, the defendant, NOVARTIS PHARMACEUTICALS CORPORATION, was and still is a business entity actually doing business in the State of New York.

28. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., is the sole shareholder and member of the defendant, WARNER-LAMBERT COMPANY LLC.

29. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, is a division of the defendant, WARNER-LAMBERT COMPANY LLC.

30. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, is a subsidiary of the defendant, WARNER-LAMBERT COMPANY LLC.

31. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, is a division of the defendant, PFIZER INC.

32. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, is a subsidiary of the defendant, PFIZER INC.

33. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, is a successor in interest to the defendant, PARKE-DAVIS.

34. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, is a division of the defendant, PFIZER INC.

35. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC. is a subsidiary of the defendant, PFIZER INC.

36. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC. is a successor in interest to the defendant, PARKE-DAVIS.

37. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, is a successor in interest to the defendant, PARKE-DAVIS.

38. That on a date prior to May 29, 2007, the defendant, WARNER-LAMBERT COMPANY, assumed the assets and liabilities of the defendant, PARKE-DAVIS.

39. That on a date prior to May 29, 2007, the defendant, WARNER-LAMBERT COMPANY, expressly assumed all liabilities and obligations of the defendant, PARKE-DAVIS.

40. That on a date prior to May 29, 2007, the defendant, WARNER-LAMBERT COMPANY, impliedly assumed all liabilities and obligations of the defendant, PARKE-DAVIS.

41. That on a date prior to May 29, 2007, the defendant, PARKE-DAVIS, and the defendant, WARNER-LAMBERT COMPANY, merged with each other.

42. That on a date prior to May 29, 2007, the defendant, PARKE-DAVIS, merged with the defendant, WARNER-LAMBERT COMPANY, and the defendant, PARKE-DAVIS, became a part of the defendant, WARNER-LAMBERT COMPANY.

43. That on a date prior to May 29, 2007, the defendant, PARKE-DAVIS, and the defendant, WARNER-LAMBERT COMPANY, consolidated with each other.

44. That on or about December 31, 2002, the defendant, WARNER-LAMBERT COMPANY LLC, assumed the assets and liabilities of the defendant, PARKE-DAVIS.

45. That on or about December 31, 2002, the defendant, WARNER-LAMBERT COMPANY LLC, expressly assumed all liabilities and obligations of the defendant, PARKE-DAVIS.

46. That on or about December 31, 2002, the defendant, WARNER-LAMBERT COMPANY LLC, impliedly assumed all liabilities and obligations of the defendant, PARKE-DAVIS.

47. That on or about December 31, 2002, the defendant, PARKE-DAVIS, and the defendant, WARNER-LAMBERT COMPANY LLC, merged with each other.

48. That on or about December 31, 2002, the defendant, PARKE-DAVIS, merged with the defendant, WARNER-LAMBERT COMPANY LLC, and the defendant, PARKE-DAVIS, became a part of the defendant, WARNER-LAMBERT COMPANY LLC.

49. That on or prior to December 31, 2002, the defendant, PARKE-DAVIS, and the defendant, WARNER-LAMBERT COMPANY LLC, consolidated with each other.

50. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, is a successor in interest to the defendant, WARNER-LAMBERT COMPANY.

51. That on or prior to December 31, 2002, the defendant, WARNER-LAMBERT COMPANY LLC, assumed the assets and liabilities of the defendant, WARNER-LAMBERT COMPANY.

52. That on or prior to December 31, 2002, the defendant, WARNER-LAMBERT COMPANY LLC. expressly assumed all liabilities and obligations of the defendant. WARNER-LAMBERT COMPANY.

53. That on or prior to December 31, 2002, the defendant, WARNER-LAMBERT COMPANY LLC, impliedly assumed all liabilities and obligations of the defendant, WARNER-LAMBERT COMPANY.

54. That on or prior to December 31, 2002, the defendant. WARNER-LAMBERT COMPANY. and the defendant, WARNER-LAMBERT COMPANY LLC, merged with each other.

55. That on or prior to December 31, 2002, the defendant, WARNER-LAMBERT COMPANY, merged with the defendant, WARNER-LAMBERT COMPANY LLC, and the defendant, WARNER-LAMBERT COMPANY, became a part of the defendant, WARNER-LAMBERT COMPANY LLC.

56. That on or prior to December 31, 2002, the defendant, WARNER-LAMBERT COMPANY, and the defendant, WARNER-LAMBERT COMPANY LLC, consolidated with each other.

57. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., is a successor in interest to the defendant, PARKE-DAVIS.

58. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., is a successor in interest to the defendant, WARNER-LAMBERT COMPANY.

59. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., is a successor in interest to the defendant, WARNER-LAMBERT COMPANY LLC.

60. That on a date prior to May 29, 2007, the defendant, PFIZER INC., assumed the assets and liabilities of the defendant, PARKE-DAVIS.

61. That on a date prior to May 29, 2007, the defendant, PFIZER INC., assumed the assets and liabilities of the defendant, WARNER-LAMBERT COMPANY.

62. That on a date prior to May 29, 2007, the defendant, PFIZER INC., expressly assumed all liabilities and obligations of the defendant, PARKE-DAVIS.

63. That on a date prior to May 29, 2007, the defendant, PFIZER INC., impliedly assumed all liabilities and obligations of the defendant, PARKE-DAVIS.

64. That on a date prior to May 29, 2007, the defendant, PFIZER INC., expressly assumed all liabilities and obligations of the defendant, WARNER-LAMBERT COMPANY.

65. That on a date prior to May 29, 2007, the defendant, PFIZER INC., impliedly assumed all liabilities and obligations of the defendant, WARNER-LAMBERT COMPANY.

66. That on or prior to December 31, 2002, the defendant, PFIZER INC., assumed the assets and liabilities of the defendant, WARNER-LAMBERT COMPANY LLC.

67. That on or prior to December 31, 2002, the defendant, PFIZER INC., expressly assumed all liabilities and obligations of the defendant, WARNER-LAMBERT COMPANY LLC.

68. That on or prior to December 31, 2002, the defendant, PFIZER INC., impliedly assumed all liabilities and obligations of the defendant WARNER-LAMBERT COMPANY LLC.

69. That on a date prior to May 29, 2007, the defendant, PFIZER INC., and the defendant, PARKE-DAVIS, merged with each other.

70. That on a date prior to May 29, 2007, the defendant, PFIZER INC., and the defendant, WARNER-LAMBERT COMPANY, merged with each other.

71. That on or before May 29, 2007, the defendant, PFIZER INC., and the defendant, WARNER-LAMBERT COMPANY LLC, merged with each other.

72. That on a date prior to May 29, 2007, the defendant, PFIZER INC., and the defendant, PARKE-DAVIS, merged with each other and the defendant, PARKE-DAVIS, became a part of the defendant, PFIZER INC.

73. That on a date prior to May 29, 2007, the defendant, PFIZER INC., and the defendant, WARNER-LAMBERT COMPANY, merged with each other and the defendant, WARNER-LAMBERT COMPANY, became a part of the defendant, PFIZER INC.

74. That on or prior to December 31, 2002, the defendant, PFIZER INC., and the defendant, WARNER-LAMBERT COMPANY LLC, merged with each other and the defendant, WARNER-LAMBERT COMPANY LLC, became a part of the defendant, PFIZER INC.

75. That on a date prior to May 29, 2007, the defendant, PFIZER INC., and the defendant, PARKE-DAVIS, consolidated with each other.

76. That on a date prior to May 29, 2007, the defendant, PFIZER INC., and the defendant, WARNER-LAMBERT COMPANY, consolidated with each other.

77. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., has its principal place of business in the State of New York.

78. In the year 2000, the defendant, PFIZER INC., acquired the defendant, WARNER-LAMBERT COMPANY, and as the result of that acquisition, the defendant, PFIZER

INC., is responsible for all liabilities resulting from the acts or omissions of the defendant, WARNER-LAMBERT COMPANY, which occurred prior to such acquisition.

79. In the year 2000, the defendant, PFIZER INC., acquired the defendant, PARKE-DAVIS, a division of Warner-Lambert Company, and as the result of that acquisition, the defendant, PFIZER INC., is responsible for all liabilities resulting from the acts or omissions of the defendant, PARKE-DAVIS, which occurred prior to such acquisition.

80. On or prior to December 31, 2002, defendant, PFIZER INC., acquired the defendant, WARNER-LAMBERT COMPANY LLC. and pursuant to the terms of and conditions of that acquisition, the defendant, PFIZER INC., is responsible for all acts or omissions of the defendant, WARNER LAMBERT-COMPANY, LLC, occurring prior to such acquisition.

81. That at all times hereinafter mentioned, upon information and belief, the defendant, NOVARTIS PHARMACEUTICALS CORPORATION, acquired and owns 100% of the shares of the defendant, SANDOZ INC.

82. That at all times hereinafter mentioned, upon information and belief, the defendant, SANDOZ INC., is a wholly owned subsidiary of the defendant, NOVARTIS PHARMACEUTICALS CORPORATION.

83. That at all times hereinafter mentioned, upon information and belief, the defendant, SANDOZ INC., owns 100% of the shares of the defendant, EON LABS, INC., and the defendant, SANDOZ INC., acquired ownership and control of the defendant, EON LABS, INC., on July 25, 2005.

84. That at all times hereinafter mentioned, upon information and belief, the defendant, EON LABS, INC., is a wholly owned subsidiary of the defendant, SANDOZ INC.

85. At all relevant times herein mentioned, the defendant, EON LABS, INC. acted in all aspects as agent and alter ego of the defendant, SANDOZ INC., and the defendant, NOVARTIS PHARMACEUTICALS CORPORATION

86. At all relevant times the Eon defendants were engaged in the business of manufacturing, packaging, marketing, distributing, promoting, and the sale of the drug gabapentin in New York, Tennessee and throughout the United States. At all relevant times, the defendant. NOVARTIS PHARMACEUTICALS CORPORATION, through the defendant, SANDOZ INC., successor in interest to the defendant, EON LABS, INC., were engaged in the business of designing. testing, manufacturing, packaging, marketing, distributing, promoting, and selling the drug gapabentin in New York, Tennessee and throughout the United States.

87. At all relevant times, collectively the Eon defendants, intentionally, recklessly and/or negligently concealed, suppressed, omitted, and misrepresented the risks, dangers, defects and disadvantages of gabapentin; and, advertised, promoted, marketed, sold and distributed gabapentin as a safe prescription medication when, in fact, the Eon defendants had reason to know, and/or did not know, that gabapentin, was not safe for its intended purposes, for the patients for whom it was prescribed, and for whom it was sold; and that gabapentin, caused serious medical problem including adverse mood and behavioral changes, and risk for suicide attempts and completed suicide.

88. Despite such knowledge, the Eon defendants, through their respective officers, directors and managing agents for the purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to properly warn plaintiff's decedent of the serious risk of adverse mood and behavior effects and risk for suicidal acts from the ingestion of gabapentin.

89. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., presently markets and sells the drug Neurontin.

90. That on a date prior to May 29, 2007, the defendant, PFIZER INC., marketed and sold the drug Neurontin.

91. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., is engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs, including Neurontin, and in pursuance of this business, transacts business within the State of New York and contracts to provide goods and services in the State of New York.

92. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., committed a tortious act inside the State of New York, which caused injury to plaintiff's decedent inside the State of Tennessee.

93. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., committed a tortious act outside the State of New York, which caused injury to plaintiff's decedent inside the State of Tennessee.

94. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., regularly does and solicits business and engages in a persistent course of conduct in the State of New York, deriving substantial revenue from goods and products consumed in the State of New York.

95. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., expects or should reasonably expect its acts to have consequences in the State of New York, and derives substantial revenue from interstate or international commerce.

96. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, presently markets and sells the drug Neurontin.

97. That on a date prior to May 29, 2007, the defendant, PARKE-DAVIS, marketed and sold the drug Neurontin.

98. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, is engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs, including Neurontin, and in pursuance of this business, transacts business within the State of New York and contracts to provide goods and services in the State of New York.

99. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, committed a tortious act inside the State of New York, which caused injury to plaintiff's decedent inside the State of Tennessee.

100. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, committed a tortious act outside the State of New York, which caused injury to plaintiff's decedent inside the State of Tennessee.

101. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, regularly does and solicits business and engages in a persistent course of conduct in the State of New York, deriving substantial revenue from goods and products consumed in the State of New York.

102. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, expects or should reasonably expect its acts to have consequences in the State of New York, and derives substantial revenue from interstate or international commerce.

103. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, presently markets and sells the drug Neurontin.

104. That on a date prior to May 29. 2007, the defendant, WARNER-LAMBERT COMPANY, marketed and sold the drug Neurontin.

105. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, is engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs, including Neurontin, and in pursuance of this business, transacts business within the State of New York and contracts to provide goods and services in the State of New York.

106. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, committed a tortious act inside the State of New York, which caused injury to plaintiff's decedent inside the State of Tennessee.

107. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, committed a tortious act outside the State of New York, which caused injury to plaintiff's decedent inside the State of Tennessee.

108. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, regularly does and solicits business and engages in a persistent course of conduct in the State of New York, deriving substantial revenue from goods and products consumed in State of New York.

109. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, expects or should reasonably expect its acts to have consequences in the State of New York, and derives substantial revenue from interstate or international commerce.

110. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, presently markets and sells the drug Neurontin.

111. That on a date prior to May 29, 2007, the defendant, WARNER-LAMBERT COMPANY LLC, marketed and sold the drug Neurontin.

112. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, is engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs, including Neurontin, and in pursuance of this business, transacts business within the State of New York.

113. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, committed a tortious act inside the State of New York, which caused injury to plaintiff's decedent inside the State of Tennessee.

114. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, committed a tortious act outside the State of New York, which caused injury to plaintiff's decedent inside the State of Tennessee.

115. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, regularly does and solicits business and engages in a persistent course of conduct in the State of New York, deriving substantial revenue from good and products consumed in the State of New York.

116. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, regularly does and solicits business and engages in a persistent course of conduct in the State of New York, deriving substantial revenue from interstate commerce.

117. That at all times hereinafter mentioned, upon information and belief, the defendant, EON LABS, INC., presently markets and sells the drug gabapentin.

118. That on a date prior to May 29, 2007, the defendant, EON LABS, INC., marketed and sold the drug gabapentin.

119. That at all times hereinafter mentioned, upon information and belief, the defendant, EON LABS, INC., is engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs, including the drug gabapentin, and in pursuance of this business, transacts business within the State of New York.

120. That at all times hereinafter mentioned, upon information and belief, the defendant, EON LABS, INC., committed a tortious act inside the State of New York, which caused injury to plaintiff's decedent inside the State of Tennessee.

121. That at all times hereinafter mentioned, upon information and belief, the defendant, EON LABS, INC., committed a tortious act outside the State of New York, which caused injury to plaintiff's decedent inside the State of Tennessee.

122. That at all times hereinafter mentioned, upon information and belief, the defendant, EON LABS, INC., regularly does and solicits business and engages in a persistent course of conduct in the State of New York, deriving substantial revenue from goods and products consumed in the State of New York.

123. That at all times hereinafter mentioned, upon information and belief, the defendant, EON LABS, INC., expects or should reasonably expects its acts to have consequences in the State of New York, and derives substantial revenue from interstate or international commerce.

124. That at all times hereinafter mentioned, upon information and belief, the defendant, SANDOZ INC., presently markets and sells the drug gabapentin.

125. That on a date prior to May 29, 2007, the defendant, SANDOZ INC., marketed and sold the drug gabapentin.

126. That at all times hereinafter mentioned, upon information and belief, the defendant, SANDOZ INC., is engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs, including the drug gabapentin, and in pursuance of this business, transacts business within the State of New York.

127. That at all times hereinafter mentioned, upon information and belief, the defendant, SANDOZ INC., committed a tortious act inside the State of New York, which caused injury to plaintiff's decedent inside the State of Tennessee.

128. That at all times hereinafter mentioned, upon information and belief, the defendant, SANDOZ INC., committed a tortious act outside the State of New York, which caused injury to plaintiff's decedent inside the State of Tennessee.

129. That at all times hereinafter mentioned, upon information and belief, the defendant, SANDOZ INC., regularly does and solicits business and engages in a persistent course of conduct in the State of New York, deriving substantial revenue from goods and products consumed in the State of New York.

130. That at all times hereinafter mentioned, upon information and belief, the defendant, SANDOZ INC., expects or should reasonably expects its acts to have consequences in the State of New York, and derives substantial revenue from interstate or international commerce.

131. That at all times hereinafter mentioned, upon information and belief, the defendant, NOVARTIS PHARMACEUTICALS CORPORATION, presently markets and sells the drug gabapentin.

132. That on a date prior to May 29, 2007, the defendant, NOVARTIS PHARMACEUTICALS CORPORATION, marketed and sold the drug gabapentin.

133. That at all times hereinafter mentioned, upon information and belief, the defendant, NOVARTIS PHARMACEUTICALS CORPORATION, is engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs, including the drug gabapentin, and in pursuance of this business, transacts business within the State of New York.

134. That at all times hereinafter mentioned, upon information and belief, the defendant, NOVARTIS PHARMACEUTICALS CORPORATION, committed a tortious act inside the State of New York, which caused injury to plaintiff's decedent inside the State of Tennessee.

135. That at all times hereinafter mentioned, upon information and belief, the defendant, NOVARTIS PHARMACEUTICALS CORPORATION, committed a tortious act outside the State of New York, which caused injury to plaintiff's decedent inside the State of Tennessee.

136. That at all times hereinafter mentioned, upon information and belief, the defendant, NOVARTIS PHARMACEUTICALS CORPORATION, regularly does and solicits business and engages in a persistent course of conduct in the State of New York, deriving substantial revenue from goods and products consumed in the State of New York.

137. That at all times hereinafter mentioned, upon information and belief, the defendant, NOVARTIS PHARMACEUTICALS CORPORATION, expects or should reasonably expects its acts to have consequences in the State of New York, and derives substantial revenue from interstate or international commerce.

BACKGROUND

STATEMENT OF THE CASE

138. Pursuant to the Food, Drug, and Cosmetic Act ("FDCA") 21 U.S.C. §§ 301 et seq.. new pharmaceutical drugs cannot be distributed in interstate commerce unless the sponsor of the drug demonstrates to the satisfaction of the Food and Drug Administration ("FDA") that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a) and (d).

139. However, the FDCA does not prevent doctors from prescribing a drug approved for a particular use for other uses that are different than those approved by the FDA ("off-label" usage).

140. Nonetheless, even though physicians may prescribe drugs for "off-label" usage, the FDCA prohibits drug manufacturers themselves from marketing and promoting a drug for a use that the FDA has not approved. 21 U.S.C. § 331(d).

141. A manufacturer illegally "misbrands" a drug if the drug's labeling includes information about unapproved uses or if the manufacturer engages directly or indirectly in marketing or promoting the drug for unapproved uses.

142. Instead, if a manufacturer desires to market and promote the drug for new uses in addition to those already approved, the materials on "off-label" usage must meet certain stringent requirements and the manufacturer must resubmit the drug to the FDA testing and approval process for the proposed new use.

143. The above-described statutory and regulatory system and process is designed to protect the public, including plaintiff's decedent, from the dangers arising from drugs which, although approved for a certain specific condition, disease or purpose, could cause injury and harm if used for an "off-label" purpose without adequate study and testing of the drug for such "off-label" usage, and to protect the public, including plaintiff's decedent, from the dangers arising from deceptive, misleading, and inaccurate advertising, marketing, and promotional materials issued directly or indirectly by the manufacturer to encourage the "off-label" usage of the drug without adequate testing and study of that drug for such "off-label" usage.

144. PARKE-DAVIS, now owned by PFIZER INC., applied for, and in December, 1993, received FDA approval to market and sell Neurontin solely for "adjunctive therapy" in the treatment of certain types of seizures in adult patients suffering from epilepsy, and the FDA approved labeling of Neurontin for that purpose and stated that the drug is only effective at 900 to 1800 milligrams per day.

145. At no time prior to plaintiff's decedent being prescribed Neurontin and gabapentin, did defendants receive FDA approval for any other use of Neurontin and gabapentin except for the above-described treatment of epilepsy or for higher dosages for any purpose, and the FDA never approved the usage of Neurontin and gabapentin at any dosage for the treatment of reflex sympathetic dystrophy (RSD).

146. Commencing in 1995, the Pfizer defendants, as the manufacturer of Neurontin, began to directly and indirectly advertise, market and promote Neurontin for additional "off-label" uses for which FDA approval had not been obtained, including treatment for reflex sympathetic dystrophy (RSD) and at higher dosages than had been tested and approved, in violation of the above-described statutory and regulatory system and process, including the

FDCA, which prohibits manufacturers from directly or indirectly advertising, marketing and promoting a drug for "off-label" usage, and instead requires that the manufacturer resubmit the drug to the FDA testing and approval process for the proposed new use and that the materials issued by the manufacturer relating to the proposed new use meet certain stringent requirements.

147. The Pfizer defendants, as the manufacturer of Neurontin, directly and indirectly advertised, marketed and promoted Neurontin for the treatment of reflex sympathetic dystrophy (RSD) and encouraged that higher dosages than those tested be prescribed, even though the Pfizer defendants knew or should have known that there were not adequate tests and studies establishing and confirming that Neurontin was safe and effective for the treatment of reflex sympathetic dystrophy (RSD) and even though the Pfizer defendants knew or should have known that there were no adequate studies showing that Neurontin was safe when prescribed at dosages higher than those approved by the FDA.

148. At all times hereinafter mentioned, upon information and belief, the Pfizer defendants marketed and promoted Neurontin for the treatment of reflex sympathetic dystrophy (RSD) even though the Pfizer defendants knew or should have known that Neurontin caused many symptoms or related risk factors associated with suicidal behavior by persons suffering from reflex sympathetic dystrophy (RSD).

149. At all times hereinafter mentioned, upon information and belief, the Pfizer defendants marketed and promoted Neurontin for the treatment of reflex sympathetic dystrophy (RSD) even though the Pfizer defendants knew or should have known that Neurontin had no effect in relieving or correcting the symptoms or causes of reflex sympathetic dystrophy (RSD).

150. The Pfizer defendants' conduct in promoting "off-label" uses of Neurontin for reflex sympathetic dystrophy (RSD) constituted a wanton, callous and reckless disregard of the

safety of the public and, in particular of persons suffering from reflex sympathetic dystrophy (RSD).

151. In promoting "off-label" uses of Neurontin, and at higher dosages than approved by the FDA, including treatment of restless leg syndrome, the Pfizer defendants acted without regard to the potential danger and harm to persons for whom the drug was prescribed for the treatment of reflex sympathetic dystrophy (RSD).

152. The Pfizer defendants actively distributed, sold and placed Neurontin into the stream of commerce and directly and indirectly advertised, marketed and promoted Neurontin as being safe and effective for the treatment of reflex sympathetic dystrophy (RSD) and in dosages higher than those approved by the FDA, even though the only approved use of Neurontin at that time was as "adjunctive therapy" for the treatment of epilepsy and even though the FDA had specified a maximum recommended dosage.

153. Neurontin is not reasonably safe and effective for the treatment of persons suffering from reflex sympathetic dystrophy (RSD), and is not reasonably safe when consumed in higher dosages than those approved by the FDA, and the Pfizer defendants' conduct of illegally advertising, marketing and promoting Neurontin for this "off-label" use was unlawful, deceptive and misleading and was in violation of the FDCA.

154. By reason of the Pfizer defendants' conduct of directly and indirectly advertising, marketing and promoting Neurontin for the treatment of reflex sympathetic dystrophy (RSD) in an unlawful manner, physicians commenced prescribing Neurontin to their patients diagnosed as suffering from reflex sympathetic dystrophy (RSD), frequently at dosages higher than those approved by the FDA.

155. Upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, was indicted in the United States District Court for the District of Massachusetts for violations of 21 U.S.C. §§ 331(a), 331(d), 333(a), 352(f)(1) and 355, and a copy of such criminal Information is annexed hereto as Exhibit "A" and incorporated into this complaint by reference.

156. Upon information and belief, on or about the 7th day of June, 2004, the defendant, WARNER-LAMBERT COMPANY LLC, formally pled guilty to all charges contained in the Information.

157. On April 6, 2005, the Eon defendants received approval from the Food and Drug Administration for its Abbreviated New Drug Application ("ANDA") to distribute gabapentin in capsule form.

158. The Eon defendants were able to obtain approval to manufacture gabapentin, the generic version of the brand name drug Neurontin, without performing their own safety and effectiveness studies by submitting an ANDA to the FDA. 21 U.S.C. § 355 et seq.

159. The ANDA process allowed the Eon defendants to submit data which demonstrated that the generic drug gabapentin is the same as the previously approved brand name drug Neurontin in regard to: active ingredients; method of administration and dosage; prescribed usage recommended in the labeling; and that the proposed drug is "bioequivalent" to the prior approved drug. 21 U.S.C. § 355(j)(2)(A).

160. In essence, in view of the regulatory scheme enacted by Congress and the FDA, the generic manufacturer adopts the studies, labeling, warnings and representations of the brand name manufacturer, without independent investigation in order to gain approval of the generic drug through an expedited process.

161. Pursuant to 21 C.F.R. § 314.70, manufacturers, such as the Eon defendants, who have received approval for a generic drug pursuant to the ANDA process, are allowed to amend a drug's labeling without receiving FDA prior approval in order to, inter alia, add or strengthen a contraindication, warning, precaution, or adverse reaction; add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product; and delete false, misleading, or unsupported indications for use or claims for effectiveness. Moreover, manufacturers such as the Eon defendants, may apply to the FDA for approval to amend a drug's labeling, subsequent to receiving the initial ANDA approval, to strengthen a contradiction, warning, precaution, etc.

162. The Eon defendants were among the generic manufacturers sued by Pfizer Defendants in the *In re Gabapentin Patent Litigation* in the United States District Court for the District Court of New Jersey and it would appear to be reasonable to assume that the Eon defendants were well aware of all facts concerning the Pfizer defendants' manufacture, sales and marketing of Neurontin, including that Neurontin was a $1.7 billion dollar drug for just the twelve-month period ending in June 2004. Further, it is reasonable to assume that a sophisticated manufacturer such as the Eon defendants also were well aware that the due to the sheer volume of recorded sales of Neurontin, and that the brand name drug was being promoted and prescribed for off-label uses and for uses other than the sole use that was approved by the FDA, namely, for treatment for epilepsy.

163. That the Eon defendants were aware of the studies, off-label usage, etc., and did not change the label, and/or failed to apply to the FDA to change the label subsequent to receiving approval of the ANDA for gabapentin, to caution against the risks concerning this off-label usage demonstrates that the Eon defendants were willing beneficiaries of, and indirectly

participated in, and continued to perpetuate the fraudulent, negligent and reckless conduct as alleged herein.

164. The drugs Neurontin and gabapentin were ineffective in the treatment of the causes and symptoms of plaintiff's decedent's reflex sympathetic dystrophy (RSD) and plaintiff's decedent sustained injury and death by reason of this reliance upon Neurontin and gabapentin to be effective in the treatment as prescribed by plaintiff's decedent's physicians of such reflex sympathetic dystrophy (RSD).

165. That at all times hereinafter mentioned, plaintiff's decedent was diagnosed by plaintiff's decedent's physician as suffering from reflex sympathetic dystrophy (RSD) and was being treated by plaintiff's decedent's physician for such reflex sympathetic dystrophy (RSD).

166. That at all times hereinafter mentioned, upon information and belief, in reliance upon defendants' direct and indirect advertising, marketing and promoting of Neurontin and gabapentin as being safe and effective for the treatment of reflex sympathetic dystrophy (RSD), plaintiff's decedent's physician prescribed Neurontin and gabapentin to treat plaintiff's decedent's reflex sympathetic dystrophy.

167. That from 7/24/99 through 12/2001, plaintiff's decedent purchased each month 270 400-milligram Neurontin capsules, from 1/2002 through 4/2000, plaintiffs' decedent purchased each month 150 800-milligram Neurontin capsules, and from 5/2002 through 2/2005 plaintiff's decedent purchased each month 360 400-milligram Neurontin capsules all of which were manufactured and distributed by the Pfizer defendants, as recommended and prescribed by plaintiff's decedent's physician.

168. That on 5/23/07 and 4/25/07, plaintiff's decedent purchased 360 400-milligram gabapentin capsules manufactured and distributed by the Eon defendants, as recommended and prescribed by plaintiff's decedent's physician.

169. That at all times hereinafter mentioned, plaintiff's decedent purchased and consumed Neurontin and gabapentin, as recommended and prescribed by plaintiff's decedent's physician and in the dosages prescribed, in an effort to control the effects of reflex sympathetic dystrophy (RSD).

170. The drugs Neurontin and gabapentin were not safe and effective for the treatment of plaintiff's decedent's reflex sympathetic dystrophy (RSD) and plaintiff's decedent sustained injury and death by reason of plaintiff's decedent's consumption of Neurontin and gabapentin as prescribed by plaintiff's decedent's physician in an effort to treat plaintiff's decedent's reflex sympathetic dystrophy (RSD).

171. The drugs Neurontin and gabapentin were ineffective in the treatment of the causes and symptoms of plaintiff's decedent's reflex sympathetic dystrophy (RSD) and plaintiff's decedent sustained injury and death by reason of this reliance upon Neurontin and gabapentin to be effective in the treatment as prescribed by plaintiff's decedent's physician of such reflex sympathetic dystrophy (RSD).

172. By reason of plaintiff's decedent's consumption of Neurontin and gabapentin in a manner and at a dosage prescribed by plaintiff's decedent's physician in an effort to treat plaintiff's decedent's reflex sympathetic dystrophy (RSD), on May 29, 2007, plaintiff's decedent committed suicide, thereby sustaining severe personal injuries and death.

173. The injuries and death sustained by plaintiff's decedent were caused by or were contributed to by plaintiff's decedent's consumption of Neurontin and gabapentin at a dosage

prescribed by plaintiff's decedent's physician for the treatment of reflex sympathetic dystrophy (RSD) in a manner consistent with the direct and indirect advertising, marketing and promoting of these drugs for such "off-label" use by defendants.

174. Moreover, defendants have an ongoing duty of pharmacovigilance. As part of this duty, defendants are required to continually monitor, test, and analyze data regarding the safety, efficacy, and prescribing practices of their marketed drugs, including Neurontin and gabapentin. Defendants continually receive reports from their own clinical trials, practicing physicians, individual patients and regulatory authorities concerning adverse events that occur in patients taking Neurontin and gabapentin and defendants' other marketed drugs. Furthermore, defendants continue to conduct clinical trials for their marketed drugs long after the drug is approved for use. Defendants have a continuing duty to inform doctors, regulatory agencies, and the public of new safety and efficacy information they learn, or should have learned, about their marketed drugs once that information becomes available to defendants, whether through defendants' clinical trials, other outside sources or pharmacovigilance activities. Specifically, when defendants learn, or should have learned, of new safety information associated with their marketed drugs, they have a duty to promptly disseminate that data to the public. Defendants also have a continuing duty to monitor epidemiology and pharmacovigilance data regarding their marketed drugs and promptly report any safety concerns that arise through epidemiologic study or data.

175. Defendants were further negligent and breached this continuing duty of pharmacovigilance with respect to plaintiff's decedent. Defendants, through clinical trials and other adverse event reports, learned that there was a serious problem of suicidality associated with Neurontin and gabapentin use and failed to inform doctors, regulatory agencies and the

public of this risk. Defendants had the means and the resources to perform their pharmacovigilance duties for the entire time Neurontin and gabapentin have been on the market in the United States.

176. Defendants failed to comply with the FDA postmarketing reporting requirements under 21 C.F.R. § 314.80(c) by, inter alia, failing to report each adverse drug experience concerning Neurontin and gabapentin that is both serious and unexpected, whether foreign or domestic, as soon as possible but in no case later than 15 calendar days after initial receipt of the information by defendants, failing to promptly investigate all adverse drug experiences concerning Neurontin and gabapentin that are the subject of these postmarketing 15-day Alert reports, failing to submit followup reports within 15 calendar days of receipt of new information or as requested by FDA, and, if additional information was not obtainable, failing to maintain records of the unsuccessful steps taken to seek additional information.

177. Defendants' failure to perform adequate pharmacovigilance and failure to comply with the postmarketing requirements of FDA regulations is evidence of defendants' negligence and constitutes negligence per se.

AS AND FOR A FIRST CAUSE OF ACTION AGAINST THE PFIZER DEFENDANTS FOR NEGLIGENCE

178. Plaintiff repeats and reiterates the allegations previously set forth herein.

179. That at all times hereinafter mentioned, the Pfizer defendants were under a duty to exercise reasonable care in the design and development of Neurontin, in particular, in the advertising, marketing and promoting of Neurontin, both directly and indirectly, to ensure that Neurontin was not used in the treatment of conditions such as reflex sympathetic dystrophy (RSD), for which it was not effective and to ensure that Neurontin was not used in a manner or to

treat conditions where the Pfizer defendants knew or should have known that the user could sustain injuries and harm from the drug.

180. That the Pfizer defendants negligently, recklessly, grossly negligently, wantonly and willfully displayed a morally culpable and conscious disregard of the rights of others in that they failed to exercise reasonable care and failed to fulfill the above-stated duty by the manner that the Pfizer defendants, directly and indirectly, advertised, marketed and promoted Neurontin for the treatment of reflex sympathetic dystrophy (RSD), even though Neurontin had not been scientifically determined to be safe for such use and even though Neurontin was, in fact, not reasonably safe for such use, and furthermore, the Pfizer defendants failed to adequately warn of the risk of suicide or aggressive, self-destructive behavior of which the Pfizer defendants knew or should have known about.

181. That the Pfizer defendants were further negligent, reckless, grossly negligent, wanton and willfully displayed a morally culpable and conscious disregard of the rights of others by manufacturing, distributing, selling, advertising, marketing and promoting Neurontin even though such drug was not safe or effective for any purpose because it caused or influenced persons using the drug for any purpose to engage in self-destructive behavior including committing suicide and committing suicide and by failing to adequately warn the public of such risks.

182. The aforesaid incident and the injuries and death sustained by plaintiff's decedent were caused by or were contributed to by the negligence, recklessness, gross negligence, wantonness, willfulness, and conscious and callous disregard of the safety of the public, including plaintiff's decedent, on the part of the Pfizer defendants in the design, manufacture, distribution, advertising, marketing and promoting of Neurontin as being safe and effective in the

treatment of reflex sympathetic dystrophy (RSD), and by inducing the public, including plaintiff's decedent, to believe that Neurontin was effective in the treatment of the causes and symptoms of reflex sympathetic dystrophy (RSD).

183. That at all times hereinafter mentioned, upon information and belief, the above-described culpable conduct by the Pfizer defendants was a proximate cause of injuries and death sustained by plaintiff's decedent.

184. That at all times hereinafter mentioned, plaintiff's decedent did not contribute to plaintiff's decedent's injuries and death by reason of any negligence or culpable conduct on plaintiff's decedent's part.

185. That as a result of the aforesaid occurrence, the injuries sustained and the death of plaintiff's decedent resulting therefrom, as aforesaid, the Next of Kin of plaintiff's decedent suffered extensive monetary and pecuniary losses and other compensatory damages, and there was also incurred and paid out necessary medical, hospital, funeral and concomitant expenses. In addition, plaintiff's decedent was deprived of a chance for effective and/or successful treatment.

186. That by reason of the foregoing, plaintiff's decedent's beneficiaries sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, plaintiff seeks punitive and exemplary damages against the Pfizer defendants in an amount to be determined upon the trial of this matter.

AS AND FOR A SECOND CAUSE OF ACTION AGAINST THE PFIZER DEFENDANTS FOR BREACH OF WARRANTY

187. Plaintiff repeats and reiterates the allegations previously set forth herein.

188. That at all times hereinafter mentioned, upon information and belief, the Pfizer defendants, by directly and indirectly advertising, marketing and promoting Neurontin for the treatment of reflex sympathetic dystrophy (RSD), and by placing this drug in the stream of commerce knowing that Neurontin would be prescribed for the treatment of reflex sympathetic dystrophy (RSD), in reliance upon the representations of the Pfizer defendants, expressly warranted to all foreseeable users of this drug, including plaintiff's decedent, that Neurontin was safe and effective for the treatment of reflex sympathetic dystrophy (RSD).

189. That the Pfizer defendants impliedly warranted in manufacturing, distributing, selling, advertising, marketing and promoting Neurontin to all foreseeable users, including plaintiff's decedent, that Neurontin was safe and effective for the purposes for which it had been placed in the stream of commerce by the Pfizer defendants, including for the treatment of reflex sympathetic dystrophy (RSD), and that Neurontin was reasonably safe, proper, merchantable and fit for the intended purposes, including for the treatment of reflex sympathetic dystrophy (RSD).

190. That at all times hereinafter mentioned, plaintiff's decedent relied upon the aforesaid express and implied warranties by the Pfizer defendants.

191. That at all times hereinafter mentioned, plaintiff's decedent's use of Neurontin prior to and up to the time of the above-described incident was consistent with the purposes for which the Pfizer defendants directly and indirectly advertised, marketed and promoted Neurontin, and plaintiff's decedent's use of Neurontin was reasonably contemplated, intended and foreseen by the Pfizer defendants at the time of the distribution and sale of Neurontin by the Pfizer defendants, and, therefore, plaintiff's decedent's use of Neurontin was within the scope of the above-described express and implied warranties.

192. The Pfizer defendants breached the aforesaid express and implied warranties because Neurontin was not safe and effective for the treatment of reflex sympathetic dystrophy (RSD); and because plaintiff's decedent's use of Neurontin for the treatment of reflex sympathetic dystrophy (RSD), caused or contributed to the incident described herein.

193. Plaintiff's decedent gave appropriate notice to the Pfizer defendants of the breach of the aforesaid express and implied warranties or such notice was otherwise excused.

194. That by reason of the foregoing, plaintiff's decedent's beneficiaries sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, plaintiff seeks punitive and exemplary damages against the Pfizer defendants in an amount to be determined upon the trial of this matter.

AS AND FOR A THIRD CAUSE OF ACTION
AGAINST THE PFIZER DEFENDANTS FOR PRODUCTS LIABILITY

195. Plaintiff repeats and reiterates the allegations previously set forth herein.

196. That at all times hereinafter mentioned, the drug Neurontin was not suited for the treatment of reflex sympathetic dystrophy (RSD), and was not safe and effective for the treatment of reflex sympathetic dystrophy (RSD), even though the Pfizer defendants directly and indirectly advertised, marketed and promoted Neurontin for such use.

197. That at all times hereinafter mentioned, the drug Neurontin was not safe and was not suited for the purposes for which the Pfizer defendants, directly and indirectly, advertised, marketed and promoted the drug at the time the Pfizer defendants designed, manufactured, distributed and sold the drug and placed the drug in the stream of commerce.

198. That at all times hereinafter mentioned, upon information and belief, the Pfizer defendants assumed a strict products liability to users and to persons using Neurontin, including

plaintiff's decedent, who sustained injuries, harm, damages and death by reason of the use of Neurontin for purposes directly and indirectly advertised, marketed, and promoted by the Pfizer defendants, including for the treatment of reflex sympathetic dystrophy (RSD).

199. That by reason of the foregoing, plaintiff's decedent's beneficiaries sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, plaintiff seeks punitive and exemplary damages against the Pfizer defendants in an amount to be determined upon the trial of this matter.

AS AND FOR A FOURTH CAUSE OF ACTION
AGAINST THE PFIZER DEFENDANTS FOR FRAUDULENT MISREPRESENTATION

200. Plaintiff repeats and reiterates the allegations previously set forth herein.

201. The Pfizer defendants materially misrepresented material facts concerning the safety and effectiveness of Neurontin in the treatment of reflex sympathetic dystrophy (RSD).

202. The Pfizer defendants' affirmative misrepresentations include but are not limited to the acts set forth in the following paragraphs.

203. In or about 1993, the Pfizer defendants submitted a new drug application (NDA) for approval of a drug called Neurontin (also known by the chemical name "gabapentin"), which was a new drug within the meaning of 21 U.S.C. § 321(p) and 21 C.F.R. § 310.3(h)(4) and (5). In that application, the Pfizer defendants sought to demonstrate the drug's safety and efficacy for, and sought approval for, use only as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy. On or about December 30, 1993, the FDA approved Neurontin for that specific use only. Because the Pfizer defendants had not sought approval of any other uses nor submitted information in its NDA which demonstrated

the safety and efficacy of Neurontin for any such uses, Neurontin was not approved for any use or condition other than that approved use.

204. Commencing in at least June of 1995 and continuing through at least the date of this incident, unapproved uses for Neurontin included post-herpetic neuralgia, painful diabetic neuralgia, anxiety disorder, social phobias, bipolar disorder, alcohol withdrawal syndrome, amyotrophic lateral sclerosis (ALS), spinal cord injury, essential tremor, restless leg syndrome, reflex sympathetic dystrophy (RSD), and migraine headaches, among other uses.

205. The Pfizer defendants did not file a new NDA seeking FDA approval for any of these unapproved uses at any time prior to the date of this incident.

206. The Pfizer defendants conducted evaluations of the market potential for certain of the unapproved uses for Neurontin, including but not limited to: post-herpetic neuralgia, painful diabetic neuralgia, anxiety disorder, social phobias, and bipolar disorder.

207. In or about the fall of 1995, the Pfizer defendants' Southeast Customer Business Unit ("SECBU") created a planning document regarding Neurontin, which included a page titled: "SECBU RIGHT ON THE MARK WITH NEURONTIN AND PAIN" over a picture of a target and listed "Neurontin for Pain Strategies" including plans for conference calls on pain and a pain consultant meeting.

208. Certain of the Pfizer defendants' annual strategic plans and other marketing planning documents for Neurontin included quarterly and annual goals, objectives, strategies and tactics for increasing sales of the unapproved uses of the drug. The marketing plans budgeted for and funded these tactics.

209. Commencing in early 1995 and continuing at least through the date of this incident, the Pfizer defendants determined not to seek FDA approval for certain unapproved uses.

210. In or about April and May of 1995, the Pfizer defendants performed a marketing assessment of proposed psychiatric indications for Neurontin. In that marketing assessment, the Pfizer defendants forecast potential revenue from Neurontin for bipolar disorder and anxiety treatment under two scenarios: with and without FDA approval. The Pfizer defendants' Neurontin Development Team and New Product Committee reviewed the potential psychiatric uses and concluded that the Pfizer defendants would not seek approval to promote and sell the drug for these unapproved uses.

211. In or about July of 1995, the Pfizer defendants' assessment of Neurontin's market potential for neuropathic pain was distributed to the Pfizer defendants' Neurontin Development Team and to the Pfizer defendants' Vice President for marketing. That assessment stated that "there is no intention to fully develop the indication at this point." Full development would have required submission of an NDA to the FDA for approval.

213. One of the principal factors the Pfizer defendants considered in determining whether to seek approval for Neurontin for other uses was the short patent protection available for Neurontin. Another factor was the negative impact such approval might generate on potential sales of another drug that the Pfizer defendants were developing. The Pfizer defendants expected this new drug would be approved by the FDA not only for epilepsy but also for a variety of uses beyond Neurontin's approved use.

214. Once Neurontin's patent expired, other companies could seek approval to distribute generic equivalents of Neurontin. Such approval, however, would be limited to the

approved therapeutic use for Neurontin set forth in the Pfizer defendants' original NDA approval for Neurontin. If the Pfizer defendants sought and obtained approval for any of the unapproved uses, then upon expiration of the patent, generic equivalents of Neurontin could also be sold for those unapproved uses. The Pfizer defendants were concerned that under those circumstances the generic equivalents would undermine sales of the new drug that was under development.

215. Commencing about June of 1995 until at least the date of this incident, by certain conduct described in greater detail below, the Pfizer defendants promoted the sale and use of Neurontin for certain conditions other than the approved use.

216. In October 1995, a member of the Pfizer defendants' Epilepsy Disease Team circulated a memorandum to a group including other senior members of the Pfizer defendants' Epilepsy Disease Team noting that data purchased from an outside vendor showed that doctors had reported that the main message of certain sales pitches (known as "details"), given by 10 of 50 of the Pfizer defendants' sales representatives for whom data was available in a two-month period, was for off-label use of Neurontin. Nine were for pain and one was for reflex sympathetic dystrophy, a painful nerve damage syndrome.

217. On or about July 10, 1996, the Pfizer defendants' sales representative met with a doctor in Monroe, Louisiana, and detailed a doctor on Neurontin for the treatment of pain.

218. Also in 1996, a sales representative created a document that stated that sales representatives could ask doctors during a Neurontin detail if they ever used other anti-epileptic drugs for painful neuropathies and could mention that approximately 35% of all Neurontin use is non-seizure. This same document, entitled "Neurontin Can Do/Can't Do," stated that sales representatives could present lunch programs on Neurontin and pain. The document indicated that it was to be forwarded to the Northcentral Customer Business Unit.

219. The Pfizer defendants employed "medical liaisons" who were presented to physicians as employees of the company's Medical and Scientific Affairs Department. On the following occasions, which are not all-inclusive, the Pfizer defendants' medical liaisons promoted Neurontin for unapproved uses:

(a) In or about June of 1996, the Pfizer defendants' sales representative requested that the Pfizer defendants' medical liaison make a presentation at Longwood Gardens in Kennett Square, Pennsylvania, to a group of physicians who were members of a local medical society.

(b) The sales representative and the medical liaison selected the topic for the presentation to the local medical society. After deciding in consultation with the sales representative that Neurontin would be the topic of the presentation, the medical liaison prepared the presentation.

(c) Among the topics of the presentation was the use of Neurontin for unapproved uses.

(d) During the presentation, in the presence of the sales representative, the medical liaison promoted the use of Neurontin in the treatment of a number of unapproved uses.

(e) After the presentation, the Pfizer defendants' Medical Director praised the event as "another great example of use of the medical liaisons" and an area business manager called it an "outstanding utilization of . . . one of the medical affairs liaisons."

220. The Pfizer defendants organized a consultant meeting at the Jupiter Beach Resort in Palm Beach, Florida, on April 19-21, 1996. Approximately 42 physicians attended the meeting, including nine physicians who made presentations relating to unapproved uses of Neurontin.

221. The Pfizer defendants invited certain doctors to this meeting based upon their history of writing a large number of prescriptions for Neurontin or similar drugs. As part of this event, the Pfizer defendants paid for accommodations and meals for the invited doctors and their spouse or guest, and paid an honorarium to each of the doctor-attendees.

222. Among the presentations made to the physicians in attendance was one relating to unapproved uses entitled "Reduction of Pain Symptoms During Treatment with Gabapentin." In the meeting's agenda, this presentation was listed as "Anticonvulsant Advances." During this presentation, Neurontin was promoted for use in the treatment of pain.

223. Another presentation made at the Jupiter Beach conference was entitled "Anticonvulsant Advances: Nonepileptic Uses of Anti Epileptic Drugs." During this presentation, Neurontin was promoted for use in the treatment of essential tremor, episodic dyscontrol and pain.

224. On or about May 8, 1996, following the Jupiter Beach conference, the Pfizer defendants circulated to employees in the Northeast region the agenda to the meeting, specifying the off-label topics, the faculty list, the attendee list and presentation abstracts discussing the off-label content of the presentations.

225. From August 1-5, 1996, the Pfizer defendants organized an "advisory board meeting," in Atlanta, Georgia, in conjunction with the 1996 Summer Olympics. The Pfizer defendants expressly instructed several of the physician speakers to address some of the unapproved uses.

226. During that meeting, the Pfizer defendants hosted doctors at the Chateau Elan Winery and Resort, in Atlanta, Georgia, and paid all the expenses for eighteen "consultants" and their spouses to attend the Olympics, including tickets to the closing ceremonies. The Pfizer

defendants already had numerous opportunities to consult with the doctors and, in fact, many of them had spoken on the Pfizer defendants' behalf at prior meetings.

227. Certain of the physician speakers promoted Neurontin for unapproved uses in their presentations.

228. On or about March 1, 1996, the Pfizer defendants sponsored a teleconference moderated by the Pfizer defendants' employee with a pain specialist as a speaker on Neurontin. The speaker promoted Neurontin for the treatment of pain to doctors participating in the teleconference.

229. In or about May, 1996, the Pfizer defendants' Medical Director held such a teleconference entitled "Neurontin, A Clinical Update" in which the Medical Director promoted off-label uses of Neurontin to the doctors participating in the teleconference.

230. The Pfizer defendants hosted dozens of "consultants" meetings between late 1995 and 1997 in which the "consultants" received payments and gratuities as well as presentations on "off-label" Neurontin use designed to change the physicians' prescription writing habits. Such consultants' meetings included, but were not limited to the following:

Topic	Location	Dates
Mastering Epilepsy	La Costa Resort, CA	July 20-23, 1995
Mastering Epilepsy	Santa Fe, NM	Nov. 16-19, 1995
Neurontin Consultants Conference	Marco Island, FL	Feb. 2-4, 1996
Pediatric Epilepsy	Hutchinson Island, FL	Feb. 9-11, 1996
Mastering Epilepsy Science	Walt Disney World, FL	Feb. 22-25, 1996
Pediatric Epilepsy	Hutchinson Island, FL	Mar. 8-10, 1996
Mastering Epilepsy	Ritz Carlton, Aspen CO	Apr. 18-21, 1996

Affective Disorders in Psychiatry	Marco Island, FL	Apr. 20, 1996
Neurological Consultants (discussed previously)	Jupiter Beach, FL	Apr. 19-21, 1996
Affective Disorder Consultants Conference	Southern Pines, NC	Apr. 27, 1996
Neuropathic Pain Conference	Palm Beach, FL	May 11, 1996
Regional Consultants Conference	Ritz Carlton, Boston, MA	May 10-11, 1996
Epilepsy Management Advisors Meeting	Sheraton Grande, Torrey Pines, La Jolla, CA	June 21-23, 1996
Epilepsy Management Use of Anti-Convulsants in Psychiatric Disorders	Rancho Bernardo, CA Short Hills, NJ	June 28-30, 1996 Oct. 18-19, 1996
Non-epileptic Uses of Neurontin	Longboat Key, FL	Nov. 6, 1996
Neurological Conditions Conference	Ritz Carlton, Atlanta, GA	Sep. 27-28, 1997

Other "consultants" meetings took place at Charleston, SC, Coconut Grove, FL, Naples, FL, Memphis, TN, Louisville, KY, Washington, DC, Aspen, CO, and other places. Hundreds, if not thousands, of physicians received kickbacks to attend these events.

231. The Pfizer defendants rewarded doctors for their advocacy of Neurontin by paying them honoraria for lending their names to scientific articles which were actually prepared and written by third parties retained by the Pfizer defendants. In 1996, the Pfizer defendants retained AMM/ADELPHI, Ltd. and Medical Education Systems, Inc., to prepare no less than twenty (20) articles for publication in various neurology and psychiatry journals. Most of these articles concerned "off-label" usage of Neurontin and were generated so that the Pfizer defendants could completely control the publications distributed pursuant to its "publications strategy." The content of these articles were actually written by non-physician technical writers

retained by the Pfizer defendants and the Pfizer defendants had the right to control the content of all the articles. The Pfizer defendants paid all expenses in connection with the creation of these publications.

232. The Pfizer defendants also founded a speakers' bureau, another method of making large and numerous payments to physicians who recommended Neurontin for "off-label" uses, together with teleconferences, dinner meetings, consultants meetings, educational seminars, and other events.

233. The Pfizer defendants utilized medical liaisons who were provided with new company slides that detailed methods to increase "off-label" use of Neurontin, including the following:

Reflex sympathetic dystrophy (RSD)

Peripheral neuropathy

Diabetic neuropathy

Trigeminal neuralgia

Post-herpetic neuralgia

Essential tremor

Restless leg syndrome (RLS)

Attention deficit disorder (ADD)

Periodic limb movement disorder

Migraine

Bipolar disorder

Amyotrophic lateral sclerosis (ALS/Lou Gehrig's Disease)

Drug or alcohol withdrawal seizures

234. The following enumerated misrepresentations, which are not intended to be all-inclusive, relating to "off-label" usage of Neurontin were routinely made to physicians with the knowledge and consent of marketing personnel of the Pfizer defendants:

a. *Bipolar Disorder.* Medical liaisons informed psychiatrists that early results from clinical trials evaluating Neurontin for the treatment of bipolar disorder indicated ninety percent (90%) response rate when Neurontin was started at 900 mg/day dosage and increased to a dosage of 4800 mg/day. No such results existed.

b. *Peripheral Neuropathy, Diabetic Neuropathy, and Other Pain Syndromes.* Medical liaisons stated that clinical trials demonstrated that Neurontin was highly effective in the treatment of various pain syndromes and that a ninety percent (90%) response rate in the treatment of pain was being reported. No such body of evidence existed. The Pfizer defendants continued to claim that physicians should use Neurontin at substantially higher doses than indicated by the labeling. Indeed, although medical liaisons routinely claimed Neurontin to be effective as monotherapy, in 1997 the FDA refused to find Neurontin as a safe and effective monotherapy.

c. *Reflex Sympathetic Dystrophy ("RSD").* Medical liaisons informed physicians that extensive evidence demonstrated the efficacy of Neurontin in the treatment of RSD. The only such evidence that existed was anecdotal reports of nominal scientific value.

d. *Attention Deficit Disorder ("ADD").* Medical liaisons were instructed to inform pediatricians that Neurontin was effective for the treatment of ADD. No data, other than occasional anecdotal evidence, supported this claim.

e. *Restless Leg Syndrome ("RLS").* RLS was another condition where the Pfizer defendants' medical liaisons were trained to refer to a growing body of data relating to the condition, when no scientific data existed.

f. *Trigeminal Neuralgia.* Although medical liaisons represented that Neurontin could treat trigeminal neuralgia, again no scientific data supported this claim with the exception of occasional anecdotal reports. No data demonstrated that Neurontin was as effective as currently available pain killers, most of which were inexpensive.

g. *Post-Herpetic Neuralgia ("PHN").* Medical liaisons were trained to tell physicians that seventy-five percent (75%) to eighty percent (80%) of all PHN patients were successfully treated with Neurontin. Once again, no clinical trial data supported such a claim.

h. *Essential Tremor Periodic Limb Movement Disorder ("ETPLMD").* Medical liaisons were trained to allege that Neurontin was effective in the treatment of these conditions. No scientific data supported such claims with the exception of anecdotal reports of nominal scientific value.

i. *Migraine.* Claims that Neurontin was effective in the treatment of migraine headaches were made by the medical liaisons and were supposedly based on early results from clinical trials. Although pilot studies had been such suggested and undertaken, no early results of clinical trials existed to support these claims. Once again, any data relating to treatment of migraines was purely anecdotal and of nominal scientific value. Most of the case reports were either created or sponsored by the Pfizer defendants.

j. *Drug and Alcohol Withdrawal Seizures.* Medical liaisons suggested that Neurontin be used in the treatment of drug and alcohol withdrawals despite the lack of any data supporting Neurontin as an effective treatment for these conditions.

235. The Pfizer defendants sponsored a 1998 study, which was scientifically valid, conducted at the Harvard Bipolar Research Program, which concluded that patients receiving Neurontin did worse than those on sugar pills, but even though the Pfizer defendants were fully aware of these results from the tests which they sponsored, the Pfizer defendants did not publish the results until two years later after a substantial number of physicians had already been induced to prescribe Neurontin and a substantial number of patients had already been induced to take Neurontin.

236. At each of the presentations known to the plaintiff concerning Neurontin on pain, at least one of the presenters expressly stated or implied that Neurontin was effective for the treatment of pain. A representative statement was made by Dr. David Longmire, a participating physician, at the Jupiter Beach Consultants Meeting in April 1996 when he stated that Neurontin was effective for the treatment of pain. Dr. Longmire repeated that statement at a May 1996 Consultants Meeting at the Ritz Carlton in Boston. Another physician participant, Dr. Steven Schacter, made a similar statement at the May 1996 meeting when he stated that "pain specialists are finding that low dosages of Neurontin are effective." Comparable statements were made by another physician participant, Dr. Bruce Nicholson, in April 1996 at the Jupiter Beach Consultants Meeting, in May 1996 at the Boston Ritz Carlton Consultants Meeting, and in June 1996 at a Philadelphia Consultants Meeting. Upon information and belief, similar statements were made at all events presented by the Pfizer defendants that discussed Neurontin's use for pain indications. These events include, but are not limited to the following events:

Topic	Date	Location
Neurontin Consultants Meeting	Apr. 19-21, 1996	Jupiter Beach, FL
Neurontin Consultants Meeting	May 3-4, 1996	Philadelphia, PA

Neurontin Consultants Meeting	May 10-11, 1996	Boston, MA
Advisory Board Meeting	Apr. 14-16, 2000	Grand Wailea Resort Hotel & Spa, Maui, HI
Merritt-Putnam Speakers Training Advanced Perspectives in the Management of Neurological and Mood Disorders	Apr. 28-30, 2000	Enchantment Resort Sedona, AZ
New Treatment Options for the Management of Pain: The Role of Anticonvulsants	Apr. 2000	Four Seasons Irving, TX
Advisory Board Meeting	May 26, 2000	Disney Yacht Club Orlando, FL
New Directions in the Understanding and Treatment of Pain	Mar. 24, 2001	Plaza Hotel New York, NY
New Directions in the Understanding and Treatment of Pain	Mar. 2-3, 2001	Hilton Novi Detroit, MI
New Directions in the Understanding and Treatment of Pain	May 4-5, 2001	Westin Galleria Houston, TX
New Directions in the Understanding and Treatment of Pain	Feb. 9-10, 2001	Harbor Court Hotel Baltimore, MD
New Directions in the Understanding and Treatment of Pain	Mar. 9-10, 2001	Fairmont Kansas City Kansas City, MO
New Directions in the Understanding and Treatment of Pain	May 11-12, 2001	Peabody Memphis Memphis, TN
New Directions in the Understanding and Treatment of Pain	Mar. 16-17, 2001	Fairmont San Francisco San Francisco, CA
Advisory Board Meeting	June 16-18, 2000	Westin Resort Hilton Head, SC
New Directions in the Understanding and Treatment of Pain	May 18-19, 2001	Sheraton Universal City Universal City, CA
New Directions in the Understanding and Treatment of Pain	May 18-19, 2001	Miami Biltmore Miami, FL

New Directions in the Understanding and Treatment of Pain	Mar. 23-24, 2001	Ritz Carlton New Orleans New Orleans, LA
New Directions in the Understanding and Treatment of Pain	Mar. 23-24, 2001	Sheraton Music City Nashville, TN
New Directions in the Understanding and Treatment of Pain	Mar. 30-31, 2001	Ritz Carlton St. Louis St. Louis, MO
New Directions in the Treatment of Neuropathic Pain	Oct. 9-11, 1998	Madeira, Portugal

237. At events produced by the Pfizer defendants, physician participants routinely stated that Neurontin was effective for the treatment of restless leg syndrome or RSD. Events presented by the Pfizer defendants that discussed Neurontin's use as a treatment for restless leg syndrome or RSD include, but are not limited to, the following event:

Topic	Date	Location
Advisory Board Meeting	Mar. 29, 2000	Hyatt Regency Hotel San Antonio, TX

238. At events produced by the Pfizer defendants, physician participants routinely stated that Neurontin was effective for the treatment of bipolar disorder. Events presented by the Pfizer defendants that discussed Neurontin's use as a treatment for bipolar disorder include, but are not limited to, the following events:

Topic	Date	Location
Advisory Board Meeting	Mar. 29, 2000	Hyatt Regency Hotel San Antonio, TX
Parke-Davis Speakers Bureau Meeting	Jan. 21-23, 2000	Fairmont Scottsdale Princess Scottsdale, AZ
Merritt-Putnam Speakers Bureau Current Perspectives in the Understanding of Neurobehavioral Disorders	Mar. 24-26, 2000	Four Seasons Regent Beverly Wilshire, Beverly Hills, CA

Merritt-Putnam Speakers Bureau	Apr. 7-9, 2000	Wyndham New Orleans at Canal Place,New Orleans,LA
Merritt-Putnam Speakers Training Advanced Perspectives in the Management of Neurological and Mood Disorders	Apr. 28-30, 2000	Enchantment Resort Sedona, AZ
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Maison Robert Boston, MA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Sunset Grill Nashville, TN
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16. 1998	Pescatore Fish Cafe Seattle, WA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 17, 1998	Patrick's Bayside Bistro St. Pete's Beach, FL
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 17, 1998	Heathman Hotel Portland, OR
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Downtown Club Philadelphia, PA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Morton's of Chicago Buckhead, Atlanta, GA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Huntington Hotel San Francisco, CA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 19, 1998	Brass Elephant Baltimore, MD
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 19, 1998	Ristorante DeGrezia New York, NY
The Use of Anticonvulsants in Psychiatry	Oct. 23-25, 1998	Barcelona, Spain

239. At events produced by the Pfizer defendants, physician participants routinely stated that Neurontin was effective for the treatment of social phobia. Events presented by the

Pfizer defendants that discussed Neurontin's use as a treatment for social phobia include, but are not limited to, the following events:

Topic	Date	Location
Advisory Board Meeting	Mar. 29, 2000	Hyatt Regency Hotel San Antonio, TX
Parke-Davis Speakers Bureau Meeting	Jan. 21-23, 2000	Fairmont Scottsdale Princess Scottsdale, AZ
Merritt-Putnam Speakers Bureau Current Perspectives in the Understanding of Neurobehavioral Disorders	Mar. 24-26, 2000	Four Seasons Regent Beverly Wilshire, Beverly Hills, CA
Merritt-Putnam Speakers Bureau	Apr. 7-9, 2000	Wyndham New Orleans at Canal Place,New Orleans,LA
Merritt-Putnam Speakers Training Advanced Perspectives in the Management of Neurological and Mood Disorders	Apr. 28-30, 2000	Enchantment Resort Sedona, AZ
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Maison Robert Boston, MA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Sunset Grill Nashville, TN
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Pescatore Fish Cafe Seattle, WA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 17, 1998	Patrick's Bayside Bistro St. Pete's Beach, FL
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 17, 1998	Heathman Hotel Portland, OR
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Downtown Club Philadelphia, PA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Morton's of Chicago Buckhead, Atlanta, GA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Huntington Hotel San Francisco, CA

1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 19, 1998	Brass Elephant Baltimore, MD
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 19, 1998	Ristorante DeGrezia New York, NY
The Use of Anticonvulsants in Psychiatry	Oct. 23-25, 1998	Barcelona, Spain

213. Without favorable results from a well-designed panic disorder clinical trial that established Neurontin's efficacy for that condition, Parke-Davis had no reasonable scientific basis for claiming that Neurontin was effective in treating panic disorder. Nonetheless, at events produced by the Pfizer defendants, physician participants routinely stated that Neurontin was effective for the treatment of panic disorder. Events presented by the Pfizer defendants that discussed Neurontin's use as a treatment for panic disorder include, but are not limited to, the following events:

Topic	Date	Location
Advisory Board Meeting	Mar. 29, 2000	Hyatt Regency Hotel San Antonio, TX
Parke-Davis Speakers Bureau Meeting	Jan. 21-23, 2000	Fairmont Scottsdale Princess Scottsdale, AZ
Merritt-Putnam Speakers Bureau Current Perspectives in the Understanding of Neurobehavioral Disorders	Mar. 24-26, 2000	Four Seasons Regent Beverly Wilshire, Beverly Hills, CA
Merritt-Putnam Speakers Bureau	Apr. 7-9, 2000	Wyndham New Orleans at Canal Place,New Orleans,LA
Merritt-Putnam Speakers Training Advanced Perspectives in the Management of Neurological and Mood Disorders	Apr. 28-30, 2000	Enchantment Resort Sedona, AZ
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Maison Robert Boston, MA

1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Sunset Grill Nashville, TN
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Pescatore Fish Cafe Seattle, WA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 17, 1998	Patrick's Bayside Bistro St. Pete's Beach, FL
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 17, 1998	Heathman Hotel Portland, OR
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Downtown Club Philadelphia, PA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Morton's of Chicago Buckhead, Atlanta, GA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Huntington Hotel San Francisco, CA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 19, 1998	Brass Elephant Baltimore, MD
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 19, 1998	Ristorante DeGrezia New York, NY
The Use of Anticonvulsants in Psychiatry	Oct. 23-25, 1998	Barcelona, Spain

240. On September 13, 1996, Parke-Davis submitted a supplemental NDA to approve Neurontin as monotherapy for partial seizures. The FDA determined the application to be non-approvable on August 26, 1997, because of insufficiency of evidence of Neurontin's effectiveness. The FDA noted that Clinical Study 945-82 failed to yield evidence of effectiveness. Parke-Davis did not make public that its application for monotherapy had been denied. Representative events at which the Pfizer defendants continued to make presentations that Neurontin was effective for monotherapy without disclosing that the FDA had denied its application for a monotherapy indication include, but are not limited to, the following events

Topic	Date	Location
Advisory Board Meeting	Mar. 29, 2000	Hyatt Regency Hotel San Antonio, TX
Monotherapy Speakers Bureau Meeting	September 1997	La Quinta Resort Palm Springs, CA

241. Thereafter, pursuant to marketing strategies and tactics developed by Parke-Davis and the Pfizer defendants, the Pfizer defendants regularly presented programs in which physician participants touted Neurontin as being effective for the treatment of migraine. Events where such presentations were made include, but are not limited to, the following events:

Topic	Date	Location
Advisory Board Meeting	Mar. 29, 2000	Hyatt Regency Hotel San Antonio, TX
Gabapentin in the Management of Migraine	May 25, 1996	Short Hills, NJ

242. Notwithstanding the FDA's refusal to increase the maximum approved dosage of Neurontin and its finding that no clinical evidence supported Neurontin's efficacy at dosages greater than 1800 mg per day, the Pfizer defendants presented numerous programs where physician participants asserted that Neurontin was effective and safe at dosages above 1800 mg. All such representations were false and misleading. Additionally, at these presentations the physician participants did not disclose the clinical trial evidence that demonstrated that there was no dose response above 1800 mg per day. The Pfizer defendants' failure to provide this information was a violation of the Pfizer defendants' duties to provide fair and balanced information, and made any prior representations about use of Neurontin at dosages greater than 1800 mg per day false and misleading. In addition to the events identified above, other events

where these false and misleading statements were made include, but are not limited to, the following events:

Topic	Date	Location
Advisory Board Meeting on Neurontin	Feb. 4-6, 2000	Royal Sonesta New Orleans, LA
Merritt-Putnam Speakers Bureau Current Perspectives in the Understanding of Neurobehavioral Disorders	Mar. 24-26, 2000	Four Seasons Regent Beverly Wilshire. Beverly Hills, CA
Advisory Board Meeting	Mar. 29, 2000	Hyatt Regency Hotel San Antonio, TX

243. On or about June 29, 2001, the FDA Division of Drug Marketing, Advertising and Communications (DDMAC) advised the Pfizer defendants that through routine monitoring and surveillance, the DDMAC has identified a slim jim (ID #NSJ5095A1) for Neurontin that is misleading and in violation of the FDCA and applicable regulations, in that this slim jim misleadingly claims improvement in quality of life (QOL) parameters based on the Neurontin Evaluation of Outcomes in Neurological Practice (NEON) study, that among other QOL parameters, the misleading presentation includes improvement in social limitations, memory difficulties, energy level, and work limitations, and that the NEON study is not considered to be substantial evidence for claims of QOL improvements because it is not a controlled study.

244. On or about July 1, 2002, the DDMAC advised the Pfizer defendants that through routine monitoring and surveillance, the DDMAC has identified a model (#NE 102254) for Neurontin (gabapentin) that is in violation of the FDCA and applicable regulations because it makes representations about Neurontin which are false or misleading, in that this suggestion of proof of the mechanism of action is false and contrary to the language in the approved product labeling that states "[t]he mechanism by which gabapentin [Neurontin] exerts its anticonvulsant

action is unknown," and that, furthermore, the full presentation of the areas of the human brain accompanied by purported "Mechanism of Action" and the prominent display of the name "Neurontin" is misleading because it suggests that Neurontin is useful for a broader range of central nervous system conditions than has been demonstrated by substantial evidence.

245. From July 1995 through at least August 5, 2002, the Pfizer defendants engaged in a marketing program to promote the use of Neurontin, and to induce physicians to prescribe Neurontin, for medical conditions for which the FDA had not approved Neurontin to be used (i.e., "unapproved" or "off-label" uses). That program included: (a) illegally promoting the sale and use of Neurontin for a variety of conditions other than the one condition for which its use was approved by the FDA and for which the Pfizer defendants had not performed the required FDA testing or established safety and efficacy, in violation of the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 331, et seq.: (b) offering and paying illegal remuneration to doctors, either directly or through third parties, to induce them to promote and prescribe Neurontin for off-label uses, in violation of the federal Anti-kickback Statute, 42 U.S.C. § 1320a-7b(b); and (c) making and/or disseminating false statements in presentations and marketing literature sales personnel provided to doctors concerning, among other things, the uses for which the FDA had approved Neurontin, the conditions for which the use of Neurontin was otherwise medically accepted and/or the existence of adequate evidence of the safety and efficacy for such use.

246. In order to avoid sanction and regulation by the FDA, the Pfizer defendants' off-label marketing scheme depended on their concealment of their involvement in off-label promotion of Neurontin, and to make it appear to the public that the Pfizer defendants did not have any hand in any discussions of off-label use. In addition, the Pfizer defendants performed off-label promotion in the semblance of legitimate consultants' meetings, continuing education

seminars, journal articles and medical education events. Also, the Pfizer defendants' involvement was hidden becuuse the Pfizer defendants hid their financial connections between the participating physicians and used the vendor participants as payment intermediaries. These activities and others described herein concealed the Pfizer defendants' off-label promotional activities, and plaintiff's decedent could not have discovered the scheme alleged herein earlier in the exercise of reasonable diligence. Much of the scheme to this day remains concealed by the Pfizer defendants.

247. In May 2003, details of the Pfizer defendants' interactions with the other participants were disclosed through the filing by a former medical liaison, Dr. David Franklin, of previously sealed materials in opposition to the Pfizer defendants' motion for summary judgment in the qui tam action. This "off-label" promotion scheme remained hidden until, the United States District Court for the District of Massachusetts Court unsealed Dr. Franklin's Amended Complaint in the qui tam case by in April or May 2002.

248. In addition, the Pfizer defendants fraudulently concealed information and documents concerning the safety and efficacy of Neurontin, in particular, information and documents indicating that the ingestion of Neurontin for off-label uses and/or at high dosages, may cause suicidal ideations, gestures and acts.

249. Any applicable statutes of limitation have been tolled by the Pfizer defendants' knowing and active concealment and denial of the facts alleged herein. Plaintiff's decedent and other members of the public who were prescribed and ingested Neurontin for off-label uses have been kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part, and could not reasonably have discovered the fraudulent nature of the Pfizer defendants' conduct, and information and documents concerning the safety

and efficacy of Neurontin, in particular, information and documents indicating that the ingestion of Neurontin for off-label uses and/or at high dosages, may cause suicidal ideations, gestures and acts. Accordingly, the Pfizer defendants are estopped from relying on any statute of limitations to defeat any of plaintiff's claims.

250. Similarly, due to the Pfizer defendants' fraudulent concealment of the aforesaid documents and/or information, the scientific and/or medical community was not apprised of vital information concerning safety and efficacy of the drug Neurontin. Furthermore, due to the aforesaid allegations, plaintiff may rely on the discovery rule in pursuit of this claim.

251. On information and belief, the Pfizer defendants' "off-label" promotion scheme continued after the filing of Dr. Franklin's whistleblower complaint and still continues. For example, through the third quarter of 2002, there were no published scientific studies to support Neurontin's use for a wide variety of diseases that it is being prescribed for including anxiety disorder, attention deficit disorder, bipolar disorder, cluster headache, depression, dosages in excess of 1800 mg per day and many other disorders that physicians are now prescribing Neurontin for that are "off-label." Despite this lack of scientific evidence, Neurontin sales for these and other "off-label" uses have steadily increased, to the point that, according to an article published in the December 1, 2003 issue of Medical Marketing & Media, 90% of Neurontin sales are for "off-label" use. No other drug in the United States has such a high percentage of "off-label" use. The same article estimates that $1.8 billion worth of Neurontin has been sold for "off-label" uses. This increase in sales, and the repeated and increased prescription of Neurontin for "off-label" uses, without any supporting scientific studies that would be prompting such use, cannot be a random event and could not occur without continuing "off-label" promotion by the Pfizer defendants' sales force.

252. As a result of the activities described above, many of which continue to occur after Dr. Franklin filed his whistleblower suit, physicians were inundated with false information about Neurontin. As a result, they continue to prescribe Neurontin for "off-label" uses for which there is no reliable scientific support.

253. On information and belief, Pfizer has a company-wide practice of marketing "off-label" indications. "Off-label" marketing plans exist for Cox 2 inhibitors and, on information and belief, also exist for Neurontin.

254. This continuing course of conduct is evidenced in part by the staggering growth of Neurontin sales for "off-label" uses. Because there are no valid scientific studies supporting such use, a reasonable inference is that the use results from past and continuing promotional efforts by the Pfizer defendants. This clear and unavoidable conclusion follows from observations regarding the ongoing extent of prescriptions written for "off-label" Neurontin use.

255. First, from the perspective of overall Neurontin sales, "off-label" usage of Neurontin has actually increased during the years since 1999; in recent years, "off-label" prescriptions for Neurontin have exceeded 90% of all sales and, in some months, it appears that approved indication usage is negligible.

256. Second, although Neurontin is prescribed for scores of "off-label" indications, since 1999 the types of "off-label" usage continue to be weighted in the precise areas where the Pfizer defendants focused their illegal marketing efforts: bipolar disorder, peripheral neuropathy, migraine, etc.

257. Third, these focus treatment areas of continuing unapproved usage are subject to very intense competition between therapeutic substitutes (other drugs or treatments). Indeed, because manufacturers' incremental cost for drugs in these areas is very small (e.g., only pennies

to manufacture an additional pill), manufacturers compete aggressively for market share by spending huge amounts of money for marketing, promotional and sales activities. If any company was to simply pack its tent and discontinue programmatic promotional effort in any therapeutic arena, significant loss of overall sales within that diagnosis regime would certainly occur. For Neurontin, no such dip in overall sales, let alone any significant drop, has occurred.

258. Fourth, Pfizer, like most branded drug companies, monitors the relationship of its sales to its promotional efforts in very short timeframe: Pfizer would be concerned about a drop in sales within a certain therapeutic regime not after a year look-back, or even a quarterly look-back, but over just weeks. The persistent maintenance of high Neurontin sales within multiple, targeted areas for "off-label" promotion over a period of years defies the conclusion that any significant backing away on the marketing, sales or promotion of Neurontin to each of those approved therapeutic areas.

259. For example, sales of Neurontin for the treatment of bipolar disorder have steadily increased since its introduction. This increase is a direct result of the Pfizer defendants' sales representatives recommending to doctors its use for this purpose and their distribution of unapproved promotional materials. These promotional efforts did not stop in 1999, but continued thereafter. There are no valid scientific studies that support Neurontin's use for bipolar disorders. Dr. C. Seth Landefeld has submitted an expert opinion in the Franklin litigation that a review of Drugdex for Neurontin, as of the end of August 2002, reveals "no published scientific studies to support Neurontin's use for . . . bipolar disorder." As a result, tens of thousands of patients who need help and could use other drugs whose effectiveness has been established, were given and are being given Neurontin. These prescriptions for this purpose are still being written

and as a direct result of the Pfizer defendants' pre-2000 illegal promotional activities and post-2000 illegal promotional activities.

260. Likewise, sales of Neurontin for pain, ALS, attention deficit disorder, depression and dosages in excess of 1800 mg per day, are also increasing without any scientific evidence supporting use of Neurontin for such indications. Again, as noted by Dr. Lundefeld, as of the end of the third quarter of 2002 "there were no published scientific studies to support Neurontin's use for" any of these indications or in an increased dose.

261. Overall, "off-label" sales of Neurontin have steadily increased since 1998, and from 2000 to the present have consistently remained at 93% to 94% of all sales. Actual sales for approved uses has declined. Given the absence of scientific support for such uses, the genesis for those sales can only be past and continuing efforts by the Pfizer defendants to promote "off-label" use.

262. The Pfizer defendants made additional fraudulent misrepresentations as to the safety and effectiveness of Neurontin, which are not detailed herein but will be determined in discovery.

263. The Pfizer defendants affirmatively and fraudulently misrepresented that Neurontin was safe and effective in the treatment of unipolar disorder (mania), bipolar disorder and attention deficit disorder, when, in actuality, Neurontin was ineffective in treating such conditions and instead influenced users to engage in self-destructive behavior.

264. The Pfizer defendants affirmatively and fraudulently misrepresented that Neurontin was safe for human consumption in general, when in actuality, Neurontin influenced users to engage in self-destructive behavior.

265. The Pfizer defendants knew that Neurontin was not safe and effective in the treatment of restless leg syndrome, and that Neurontin was not safe for human consumption in general because such drug influenced users to engage in self-destructive behavior.

266. The Pfizer defendants knew that physicians, health care providers, and mental health care providers would justifiably rely upon the Pfizer defendants' misrepresentations in prescribing Neurontin in the treatment of restless leg syndrome, and in prescribing Neurontin for human consumption in general for the treatment of illnesses and medical and mental conditions and that the public, including persons such as plaintiff's decedent would justifiably rely upon the Pfizer defendants' misrepresentations in using Neurontin as prescribed by physicians, health care providers and mental health care providers in the treatment of unipolar disorder (mania), bipolar disorder and attention deficit disorder, and for other prescribed uses.

267. Plaintiff's decedent justifiably relied upon the Pfizer defendants' misrepresentations and, accordingly, consumed Neurontin as prescribed by plaintiff's decedent's physician in the treatment of reflex sympathetic dystrophy (RSD).

268. By reason of plaintiff's decedent's consumption of Neurontin in justifiable reliance upon the Pfizer defendants' fraudulent misrepresentations, plaintiff's decedent sustained injuries and was caused to commit suicide.

269. That by reason of the foregoing, plaintiff's decedent's beneficiaries sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, plaintiff seeks punitive and exemplary damages against the Pfizer defendants in an amount to be determined upon the trial of this matter.

AS AND FOR A FIFTH CAUSE OF ACTION AGAINST THE PFIZER DEFENDANTS FOR VIOLATION OF TENNESSEE CONSUMER PROTECTION STATUTES

270. Plaintiff repeats and reiterates the allegations previously set forth herein.

271. The Pfizer defendants knowingly, willfully and intentionally engaged in unlawful, unfair, unconscionable, deceptive and fraudulent acts and practices injurious to the public interest, in violation of Tennessee Consumer Protection Act, Tenn. Code Ann. § 47-18-101, et seq., for the purpose of influencing and inducing physicians and medical providers to prescribe Neurontin, at excessively high dosages, for unapproved "off-label" uses, including treatment for reflex sympathetic dystrophy (RSD), to patients/consumers such as the plaintiff's decedent, and taking advantage of the lack of knowledge, ability, experience or capacity of such patients/consumers to a grossly unfair degree, and causing such patients/consumers to purchase, acquire and use Neurontin, at high dosages, for unapproved "off-label" uses, including treatment for reflex sympathetic dystrophy (RSD), as prescribed by their physicians and medical providers.

272. By reason of the Pfizer defendants' unlawful, unfair, unconscionable, deceptive and fraudulent acts and practices, reasonable patients/consumers acting reasonably, such as plaintiff's decedent, were caused to commit suicide and to sustain actual damages.

273. By reason of the foregoing, plaintiff's decedent's beneficiaries sustained actual damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdictional limits of this matter, and in addition thereto, plaintiff seeks reasonable attorney's fees and costs.

AS AND FOR A SIXTH CAUSE OF ACTION AGAINST THE EON DEFENDANTS FOR NEGLIGENCE

274. Plaintiff repeats and reiterates the allegations previously set forth herein.

275. That at all times hereinafter mentioned, the Eon defendants were under a duty to exercise reasonable care in the design and development of gabapentin, in particular, by adopting the statements, studies, labeling and representations of the brand name manufacturer of Neurontin, in the advertising, marketing and promoting of gabapentin, both directly and indirectly, to ensure that gabapentin was not used in the treatment of conditions such as reflex sympathetic dystrophy (RSD), for which it was not effective and to ensure that gabapentin was not used in a manner or to treat conditions where the Eon defendants knew or should have known that the user could sustain injuries and harm from the drug.

276. That the Eon defendants negligently, recklessly, grossly negligently, wantonly and willfully displayed a morally culpable and conscious disregard of the rights of others in that they failed to exercise reasonable care and failed to fulfill the above-stated duty by the manner that the Eon defendants, by adopting the statements, studies, labeling and representations of the brand name manufacturer of Neurontin, directly and indirectly, advertised, marketed and promoted gabapentin for the treatment of reflex sympathetic dystrophy (RSD), even though gabapentin had not been scientifically determined to be safe for such use and even though gabapentin was, in fact, not reasonably safe for such use, and furthermore, the Eon defendants failed to adequately warn of the risk of suicide or aggressive, self-destructive behavior of which the Eon defendants knew or should have known about.

277. That the Eon defendants were further negligent, reckless, grossly negligent, wanton and willfully displayed a morally culpable and conscious disregard of the rights of others by manufacturing, distributing, selling, advertising, marketing and promoting gabapentin even though such drug was not safe or effective for any purpose because it caused or influenced

persons using the drug for any purpose to engage in self- destructive behavior including committing suicide and by failing to adequately warn the public of such risks.

278. The aforesaid incident and the injuries and death sustained by plaintiff's decedent were caused by or were contributed to by the negligence, recklessness, gross negligence, wantonness, willfulness, and conscious and callous disregard of the safety of the public, including plaintiff's decedent, on the part of the Eon defendants, by adopting the statements, studies, labeling and representations of the brand name manufacturer of Neurontin, in the design, manufacture, distribution, advertising, marketing and promoting of gabapentin as being safe and effective in the treatment of reflex sympathetic dystrophy (RSD), and by inducing the public, including plaintiff, to believe that gabapentin was effective in the treatment of the causes and symptoms of reflex sympathetic dystrophy (RSD).

279. That at all times hereinafter mentioned, upon information and belief, the above-described culpable conduct by the Eon defendants was a proximate cause of plaintiff's decedent's committing suicide and the injuries sustained and death of plaintiff's decedent flowing therefrom.

280. That at all times hereinafter mentioned, plaintiff's decedent did not contribute to plaintiff's decedent's injuries or death by reason of any negligence or culpable conduct on plaintiff's decedent's part.

281. That by reason of the foregoing, plaintiff's decedent's beneficiaries sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, plaintiff seeks punitive and exemplary damages against the Eon defendants in an amount to be determined upon the trial of this matter.

AS AND FOR A SEVENTH CAUSE OF ACTION
AGAINST THE EON DEFENDANTS FOR BREACH OF WARRANTY

282. Plaintiff repeats and reitcrates the allegations previously set forth herein.

283. That at all times hereinafter mentioned, upon information and belief, the Eon defendants, by adopting the statements, studies, labeling and representations of the brand name manufacturer of Neurontin, by directly and indirectly advertising, marketing and promoting gabapentin for the treatment of reflex sympathetic dystrophy (RSD), and by placing this drug in the stream of commerce knowing that gabapentin would be prescribed for the treatment of reflex sympathetic dystrophy (RSD), in reliance upon the representations of the Pfizer defendants, expressly warranted to all foreseeable users of this drug, including plaintiff's decedent, that gabapentin was safe and effective for the treatment of reflex sympathetic dystrophy (RSD).

284. That the Eon defendants, by adopting the statements, studies, labeling and representations of the brand name manufacturer of Neurontin, impliedly warranted in manufacturing, distributing, selling, advertising, marketing and promoting gabapentin to all foreseeable users, including plaintiff's decedent, that gabapentin was safe and effective for the purposes for which it had been placed in the stream of commerce by the Eon defendants, including for the treatment of reflex sympathetic dystrophy (RSD), and that gabapentin was reasonably safe, proper, merchantable and fit for the intended purposes, including for the treatment of reflex sympathetic dystrophy (RSD).

285. That at all times hereinafter mentioned, plaintiff's decedent relied upon the aforesaid express and implied warranties by the Eon defendants.

286. That at all times hereinafter mentioned, plaintiff's decedent's use of gabapentin prior to and up to the time of the above-described incident was consistent with the purposes for which the Eon defendants directly and indirectly advertised, marketed and promoted gabapentin,

and plaintiff's decedent's use of gabapentin was reasonably contemplated, intended and foreseen by the Eon defendants at the time of the distribution and sale of gabapentin by the Eon defendants, and, therefore, plaintiff's decedent's use of gabapentin was within the scope of the above-described express and implied warranties.

287. The Eon defendants breached the aforesaid express and implied warranties because gabapentin was not safe and effective for the treatment of reflex sympathetic dystrophy (RSD), and because plaintiff's decedent's use of gabapentin for the treatment of reflex sympathetic dystrophy (RSD) caused or contributed to the incident described herein.

288. Plaintiff's decedent gave appropriate notice to the Eon defendants of the breach of the aforesaid express and implied warranties or such notice was otherwise excused.

289. That by reason of the foregoing, plaintiff's decedent's beneficiaries sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, plaintiff seeks punitive and exemplary damages against the Eon defendants in an amount to be determined upon the trial of this matter.

AS AND FOR AN EIGHTH CAUSE OF ACTION
AGAINST THE EON DEFENDANTS FOR PRODUCTS LIABILITY

290. Plaintiff repeats and reiterates the allegations previously set forth herein.

291. That at all times hereinafter mentioned, the drug gabapentin was not suited for the treatment of reflex sympathetic dystrophy (RSD), and was not safe and effective for the treatment of reflex sympathetic dystrophy (RSD), even though the Eon defendants directly and indirectly advertised, marketed and promoted gabapentin for such use.

292. That at all times hereinafter mentioned, the drug gabapentin was not safe and was not suited for the purposes for which the Eon defendants, directly and indirectly, advertised,

marketed and promoted the drug at the time the Eon defendants designed, manufactured, distributed and sold the drug and placed the drug in the stream of commerce.

293. That at all times hereinafter mentioned, upon information and belief, the Eon defendants assumed a strict products liability to users and to persons using gabapentin, including plaintiff's decedent , who sustained injuries. harm and damages by reason of the use of gabapentin for purposes directly and indirectly advertised, marketed, and promoted by the Eon defendants, including for the treatment of reflex sympathetic dystrophy (RSD).

294. That by reason of the foregoing, plaintiff's decedent's beneficiaries sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, plaintiff seeks punitive and exemplary damages against the Eon defendants in an amount to be determined upon the trial of this matter.

AS AND FOR A NINTH CAUSE OF ACTION AGAINST ALL DEFENDANTS

295. Plaintiff repeats and reiterates the allegations previously set forth herein.

296. That at the time of the incident and during plaintiff's decedent's consumption of Neurontin and gabapentin prior to and until the time of his death, plaintiff's decedent suffered suicidal ideations and apprehension of death during a period of time leading up to the actual commission of suicide.

297. That for a period of time leading up to and at the time of the aforesaid suicide, plaintiff's decedent lived and was suffering excruciating mental anguish, severe pain and suffering.

298. That by reason of the foregoing, plaintiff's decedent's beneficiaries sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have

jurisdiction of this matter, and in addition thereto, plaintiff seeks punitive and exemplary damages against defendants in an amount to be determined upon the trial of this matter.

WHEREFORE, plaintiff demands judgment against the defendants as follows:

(1) A sum which exceeds the jurisdictional limits of all lower courts which the jury would find to be fair, adequate and just on the First Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action:

(2) A sum which exceeds the jurisdictional limits of all lower courts which the jury would find to be fair, adequate and just on the Second Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(3) A sum which exceeds the jurisdictional limits of all lower courts which the jury would find to be fair, adequate and just on the Third Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(4) A sum which exceeds the jurisdictional limits of all lower courts which the jury would find to be fair, adequate and just on the Fourth Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(5) Actual damages sustained on the Fifth Cause of Action, and, in addition, plaintiff seeks punitive damages and exemplary damages in an amount to be determined upon the trial of this Action, and reasonable attorney's fees and costs;

(6) A sum which exceeds the jurisdictional limits of all lower courts which the jury would find to be fair, adequate and just on the Sixth Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(7) A sum which exceeds the jurisdictional limits of all lower courts which the jury would find to be fair, adequate and just on the Seventh Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(8) A sum which exceeds the jurisdictional limits of all lower courts which the jury would find to be fair, adequate and just on the Eighth Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action; and

(9) A sum which exceeds the jurisdictional limits of all lower courts which the jury would find to be fair, adequate and just on the Ninth Cause of Action together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action; together with the interest, costs and disbursements of this Action.

Dated: May 28, 2008

Yours, etc.,

FINKELSTEIN & PARTNERS, LLP
Attorneys for Plaintiff
Office & P.O. Address
436 Robinson Avenue
Newburgh, New York 12550

BY: _____
ANDREW G. FINKELSTEIN, ESQ.

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Of Counsel to the Offices of
BROWN & CROUPPEN, P.C.
Laclede Gas Bldg.
720 Olive Street, Suite 1800
St. Louis, MO 63101

TO: PFIZER INC.
Defendant
c/o Secretary of State
1 Commerce Place
Albany, New York 12260

PARKE-DAVIS, a division of
Warner-Lambert Company and
Warner-Lambert Company LLC
Defendant
150 E. 42nd Street
New York, New York

WARNER-LAMBERT COMPANY
Defendant
150 E. 42nd Street
New York, New York

WARNER-LAMBERT COMPANY LLC
Defendant
c/o Secretary of State
1 Commerce Place
Albany, New York 12260

EON LABS, INC.
Defendant
c/o Secretary of State
1 Commerce Place
Albany, New York 12260

SANDOZ INC.
Defendant
c/o Secretary of State
1 Commerce Place
Albany, New York 12260

NOVARTIS PHARMACEUTICALS CORPORATION
Defendant
c/o Secretary of State
1 Commerce Place
Albany, New York 12260

STATE OF NEW YORK, COUNTY OF ORANGE ss:

I, the undersigned, am an attorney admitted to practice in the courts of New York State, and say that:

I am the attorney of record, or of counsel with the attorney(s) of record, for the plaintiff. I have read the annexed Verified Complaint know the contents thereof and the same are true to my knowledge, except those matters therein which are stated to be alleged on information and belief, and as to those matters I believe them to be true.

My belief, as to those matters therein not stated upon knowledge, is based upon the following:

Facts and information contained in deponent's file. The reason I make this affirmation instead of the plaintiff is because the plaintiff resides outside of the county where deponent maintains his office.

I affirm that the foregoing statements are true under penalties of perjury.

Dated: May 28, 2008

ANDREW G. FINKELSTEIN, ESQ.

STATE OF TENNESSEE
PROBATE COURT OF DICKSON COUNTY
AT CHARLOTTE

CASE NUMBER
05-08-052-P

LETTERS OF ADMINISTRATION

To: ANN MONSUE Address: 245 PATE LANE DICKSON, TN. 37055

To: _____ Address: _____

A citizen of DICKSON County

It appearing to the Probate Court that CLYDE MONSUE has died leaving no will, and said Court having appointed the above named Administrator/Administratrix upon making bond and qualifying as directed by law:

It is therefore, ordered that Letters of Administration are hereby issued to the above named Administrator/Administratrix being now empowered to enter into and take possession of all property rights and credits of this deceased person, and to administer this estate as required by law.

In witness whereof, I have issued these Letters of Administration.

Date: 05-21-08

Judy H. Wilson SH
Probate Court Clerk

OATH

I do solemnly swear that I will honestly and faithfully discharge the duties imposed on me, including the filing of inventory, settlement, inheritance tax return and affidavits, as required by law.

Ann T Monsue
Administrator/Administratrix

Administrator/Administratrix

Subscribed and sworn to before me: 05-21-08 Judy H. Wilson SA
Probate Court Clerk

I, Probate Court Clerk, certify that:

1) this is a Court of Record;
2) the above is a true, full and correct copy of the Letters of Administration issued by this Court in this estate;
3) these Letters are still in full force and effect as of this date.

Date: 05-21-08 Judy H. Wilson SA.
Probate Court Clerk

EXHIBIT "A"

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA Plaintiff, v. WARNER-LAMBERT COMPANY LLC Defendant.	Crim. No. Violations: Title 21, United States Code Sections 331(a), 331(d), 352(f)(1), and 355(a)

INFORMATION

THE UNITED STATES ATTORNEY FOR THE DISTRICT OF MASSACHUSETTS CHARGES THAT:

GENERAL ALLEGATIONS

At all times material to this Information, unless otherwise alleged:

BACKGROUND

1. WARNER-LAMBERT COMPANY LLC (hereinafter "WARNER-LAMBERT"), was a corporation operating and existing under the laws of the State of Delaware. Its principal place of business was Morris Plains, New Jersey. WARNER-LAMBERT's Parke-Davis Division was engaged in, among other things, the development, manufacture, promotion, sale, and interstate distribution of prescription drugs intended for human use in the United States. WARNER-LAMBERT's pharmaceutical manufacturing facilities were located in Puerto Rico, from which it shipped products to all fifty states and the District of Columbia.

2. The Federal Food, Drug and Cosmetic Act ("FDCA"), among other things governs the lawful interstate distribution of drugs for human use. As codified at Title 21, United States Code, Sections 331 et seq., and specifically at § 355(b), the FDCA, and its implementing regulations, require that before a new drug may legally be distributed in interstate commerce, a sponsor of a new drug product must submit a New Drug Application ("NDA").

3. The FDCA required, at 21 U.S.C. § 355, that the NDA sponsor submit to the United States Food and Drug Administration ("FDA"), as part of an NDA, proposed labeling for the proposed intended uses for the drug which included, among other things, the conditions for therapeutic use. The NDA must also provide, to the satisfaction of FDA, data generated in

randomized and well-controlled clinical trials that demonstrates that the drug will be safe and effective when used in accordance with the proposed labeling.

4. The FDCA, at 21 U.S.C. § 355, prohibited the introduction into interstate commerce of any new drug, unless an approval of an NDA is effective. Only after the NDA, including the proposed labeling, was reviewed and approved by FDA, was the sponsor permitted by law to promote and market the drug, and only for the medical conditions of use specified in the approved labeling, for which use FDA had found sufficient evidence of safety and effectiveness. Uses unapproved by FDA, not included in the drug's approved labeling, are known as "unapproved uses" or "off-label uses."

5. The FDCA, and the regulations promulgated thereunder, required that in order to label or promote a drug for a use different than the conditions for use specified in the approved labeling, the sponsor had to file a new NDA, or amend the existing NDA, by, among other requirements, submitting the newly proposed indications for use and evidence, in the form of randomized and well-controlled clinical studies, sufficient to demonstrate that the drug would be safe and effective for the newly proposed therapeutic use or uses. Only upon approval of the new NDA could the sponsor promote the drug for the new intended use.

6. The FDCA, at 21 U.S.C. § 352(f)(1), provided that a drug was misbranded if, among other things, the labeling did not contain adequate directions for use. As the phrase is used in the FDCA, adequate directions for use cannot be written for medical indications or uses for which the drug had not been proven to be safe and effective through well-controlled clinical studies because that would be misleading under Section 352(a).

7. The FDCA, 21, U.S.C. §§ 331(a)(d), 333(a), and 355, prohibits the distribution in interstate commerce of an unapproved new drug or of a misbranded drug.

8. In or about 1993, WARNER-LAMBERT submitted an NDA for approval of a drug called Neurontin (also known by the chemical name gabapentin), which was a new drug within the meaning of 21 U.S.C. § 321(p) and 21 C.F.R.§ 310.3 (h)(4) and (5) . In that application, WARNER-LAMBERT sought to demonstrate the drug's safety and efficacy for, and sought approval for, use only as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy. On or about December 30, 1993, FDA approved Neurontin for that specific use only. This approved use for Neurontin will be referred to throughout this Information as the "Approved Use." Because WARNER-LAMBERT had not sought approval of any other uses nor submitted information in its NDA which demonstrated the safety and efficacy of Neurontin for any such uses, Neurontin was not approved for any use or condition other than the Approved Use. Further, Neurontin was not, pursuant to 21 U.S.C. § 355(i), exempt from the prohibition of introducing into interstate commerce a new drug for medical indications beyond the conditions prescribed, recommended, or suggested in the approved labeling thereof.

9. As described in this Information, from at least June of 1995 through at least August 20, 1996, unapproved uses for Neurontin included post-herpetic neuralgia, painful diabetic neuralgia, anxiety disorder, social phobias, bipolar disorder, alcohol withdrawal syndrome, amyotrophic lateral sclerosis (ALS), spinal cord injury, essential tremor, restless leg syndrome, reflex sympathetic dystrophy (RSD); and migraine headaches, among other uses.

These and other unapproved uses for Neurontin will be collectively referred to in this Information as the "Unapproved Uses."

10. WARNER-LAMBERT did not file a new NDA seeking FDA approval for any of these Unapproved Uses during the time period addressed in this Information. Of these Unapproved Uses, only post-herpetic neuralgia has ever received FDA approval, and that approval was applied for and received after the events described in this Information.

WARNER-LAMBERT'S STRATEGY FOR NEURONTIN

11. WARNER-LAMBERT conducted evaluations of the market potential for certain of the Unapproved Uses for Neurontin, including but not limited to: post-herpetic neuralgia, painful diabetic neuralgia, anxiety disorder, social phobias, and bipolar disorder.

12. In or about the fall of 1995, WARNER-LAMBERT's Southeast Customer Business Unit ("SECBU") created a planning document regarding Neurontin, which included a page titled: "SECBU RIGHT ON THE MARK WITH NEURONTIN AND PAIN" over a picture of a target and listed "Neurontin for Pain Strategies" including conference calls on pain and a pain consultant meeting.

13. Certain of WARNER-LAMBERT's annual strategic plans and other marketing planning documents for Neurontin included quarterly and annual goals, objectives, strategies, and tactics for increasing sales of the Unapproved Uses of the drug. The marketing plans budgeted for and funded these tactics.

14. From early 1995, on repeated occasions, WARNER-LAMBERT determined not to seek FDA approval for certain Unapproved Uses.

15. In or about April and May of 1995, WARNER-LAMBERT performed a Marketing Assessment of proposed psychiatric indications for Neurontin. In that Marketing Assessment, WARNER-LAMBERT forecast potential revenue from Neurontin for bipolar and anxiety treatment under two scenarios: with and without FDA approval. WARNER-LAMBERT's Neurontin Development Team and New Product Committee reviewed the potential psychiatric uses and concluded that the company would not seek approval to promote and sell the drug for these Unapproved Uses.

16. In or about July of 1995 WARNER-LAMBERT's assessment of Neurontin's market potential for neuropathic pain was distributed to its Neurontin Development Team and to a WARNER-LAMBERT Vice President for Marketing. That assessment stated that "there is no intention to fully develop the indication at this point." Full development would have required submission of an NDA to FDA for approval.

17. One of the principal factors WARNER-LAMBERT considered in determining whether to seek approval for Neurontin for other uses was the short patent protection available for Neurontin. Another factor was the negative impact such approval might generate on potential sales of another drug that WARNER-LAMBERT had been developing. The company expected this new drug would be approved by FDA not only for epilepsy but also for a variety of uses beyond Neurontin's Approved Use.

18. Once Neurontin's patent expired, other companies could seek approval to distribute generic equivalents of Neurontin. Such approval, however, would be limited to the approved therapeutic use for Neurontin set forth in WARNER-LAMBERT's original NDA approval for Neurontin. If WARNER-LAMBERT sought and obtained approval for any of the

Unapproved Uses, then upon expiration of the patent, generic equivalents of Neurontin could also be sold for those Unapproved Uses. WARNER-LAMBERT was concerned that under those circumstances the generic equivalents would undermine sales of the new drug that was under development.

WARNER-LAMBERT'S PROMOTION OF NEURONTIN FOR UNAPPROVED USES

19. From in or about June of 1995 through in or about August 20, 1996, by certain of the conduct described in greater detail below, WARNER-LAMBERT promoted the sale and use of Neurontin for certain conditions other than the Approved Use in Massachusetts and elsewhere:

OFF-LABEL PROMOTION THROUGH SALES REPRESENTATIVES

20. In October 1995, a member of WARNER-LAMBERT's Epilepsy Disease Team circulated a memorandum to a group including other senior members of WARNER-LAMBERT's Epilepsy Disease Team noting that data purchased from an outside vendor showed that doctors had reported that the main message of certain sales pitches (known as "details"), given by 10 of 50 WARNER-LAMBERT sales representatives for whom data was available in a two month period, was for off-label use of Neurontin. Nine were for pain and one was for reflex sympathetic dystrophy, a painful nerve damage syndrome.

21. On or about July 10, 1996, a WARNER-LAMBERT sales representative met with a doctor in Monroe, Louisiana, and detailed a doctor on Neurontin for the treatment of pain.

22. Also in 1996, a sales representative created a document that stated that sales representatives could ask doctors during a Neurontin detail if they ever used other anti-epileptic drugs for painful neuropathies and could mention that approximately 35% of all Neurontin use is non-seizure. This same document, entitled "Neurontin Can Do/Can't Do," stated that sales

representatives could do lunch programs on Neurontin and pain. The document indicated that it was to be forwarded to the Northcentral Customer Business Unit.

OFF-LABEL PROMOTION THROUGH MEDICAL LIAISONS

23. WARNER-LAMBERT employed "medical liaisons" who were presented to physicians as employees of the company's Medical and Scientific Affairs Department. On the following occasion, a WARNER-LAMBERT medical liaison promoted Neurontin for Unapproved Uses:

(a) In or about June of 1996, a WARNER-LAMBERT sales representative requested that a WARNER-LAMBERT medical liaison make a presentation at Longwood Gardens in Kennett Square, Pennsylvania, to a group of physicians who were members of a local medical society.

(b) The sales representative and the medical liaison selected the topic for the presentation to the local medical society. After deciding in consultation with the sales representative that Neurontin would be the topic of the presentation, the medical liaison prepared the presentation.

(c) Among the topics of the presentation was the use of Neurontin for Unapproved Uses.

(d) During the presentation, in the presence of the sales representative, the medical liaison promoted the use of Neurontin in the treatment of a number of Unapproved Uses.

(e) After the presentation, a WARNER-LAMBERT Medical Director praised the event as "another great example of use of the medical liaisons" and an Area Business Manager called it an "outstanding utilization of . . . one of the medical affairs liaisons."

24. In or about May 1996, a WARNER-LAMBERT Medical Director based in the Northeast CBU sent a voicemail message to the Medical Liaisons in the Northeast CBU in which he stated:

> What we'd like you to do is, any time you're called out just make sure that your main focus out of what you're doing is on Neurontin . . . When we get out there, we want to kick some ass, we want to sell Neurontin on pain. All right? And monotherapy and everything that we can talk about, that's what we want to do.

One or more Medical Liaisons in the Northeast CBU interpreted this statement to mean that he or she should promote Neurontin for Unapproved Uses and thereafter, in or about May and June 1996, promoted Neurontin for neuropathic pain, an unapproved use.

OFF-LABEL PROMOTION THROUGH CONSULTANTS' MEETINGS AND ADVISORY BOARDS

25. WARNER-LAMBERT organized a consultant meeting at the Jupiter Beach Resort in Palm Beach, Florida on April 19-21, 1996. Approximately 42 physicians attended the meeting, including nine physicians who made presentations relating to Unapproved Uses of Neurontin.

26. WARNER-LAMBERT invited certain doctors to this meeting based upon their history of writing a large number of prescriptions for Neurontin or similar drugs. As part of this event, WARNER-LAMBERT paid for accommodations and meals for the invited doctors and

their spouse or guest, and paid an honorarium to each of the doctor attendees. Doctors who acted as faculty were paid between $1,500 and $2,000.

27. Among the presentations made to the physicians in attendance was one relating to Unapproved Uses entitled "Reduction of Pain Symptoms During Treatment with Gabapentin." In the meeting's agenda, this presentation was listed as "Anticonvulsant Advances." During this presentation, Neurontin was promoted for use in the treatment of pain.

28. Another presentation made at the Jupiter Beach conference was entitled "Anticonvulsant Advances: Nonepileptic Uses of Anti Epileptic Drugs." During this presentation, Neurontin was promoted for use in the treatment of essential tremor, episodic dyscontrol, and pain.

29. On or about May 8, 1996, following the Jupiter Beach conference, WARNER-LAMBERT circulated to employees in the Northeast region the agenda to the meeting, specifying the off-label topics, the faculty list, the attendee list and presentation abstracts discussing the off-label content of the presentations. WARNER-LAMBERT told its employees that: "[t]he meeting was a great success and the participants were delivered a hard-hitting message about Neurontin." WARNER-LAMBERT distributed to these employees a form entitled "Jupiter Beach Trending Worksheet" which was intended to be used to gauge the effect of the meeting on the prescribing by doctors who attended the Jupiter Beach meeting.

30. From August 1-5, 1996, WARNER-LAMBERT organized an "advisory board meeting," in Atlanta, Georgia in conjunction with the 1996 Summer Olympics. WARNER-LAMBERT expressly instructed several of the physician speakers to address some of the Unapproved Uses.

31. During that meeting, WARNER-LAMBERT hosted doctors at the Chateau Elan Winery and Resort, in Atlanta, Georgia, and paid all the expenses for eighteen "consultants" and their spouses to attend the Olympics, including tickets to the closing ceremonies. The company had already had numerous opportunities to consult with the doctors and, in fact, many of them had spoken on WARNER-LAMBERT's behalf at prior meetings.

32. Certain of the physician speakers promoted Neurontin for unapproved uses in their presentations.

OFF-LABEL PROMOTION THROUGH TELECONFERENCES

33. In or about January, 1996, a WARNER-LAMBERT Vice President of the Southeast Customer Business Unit sent a memorandum to WARNER-LAMBERT sales representatives listing certain goals, including: "Utilize the Medical Liaison Group to target the Neurontin, Pain & Psychiatric market. Objective to conduct twice weekly Pain Teleconferences moderated by key Neuro Consultants. Goals 250 Physicians Participants quarterly."

34. On or about March 1, 1996, WARNER-LAMBERT sponsored such a teleconference moderated by a WARNER-LAMBERT employee with a pain specialist as a speaker on Neurontin. The speaker promoted Neurontin for the treatment of pain to doctors participating in the teleconference.

35. On or about March 28, 1996, a WARNER-LAMBERT Medical Director in the Northcentral Customer Business Unit sent a memorandum to WARNER-LAMBERT Medical Liaisons in that unit instructing them to hold a series of teleconferences with doctors to provide clinical updates on Neurontin, including monotherapy epilepsy data and non-epilepsy use data entitled "Neurontin, A Clinical Update."

36. In or about May, 1996, a WARNER-LAMBERT Medical Director held such a teleconference entitled "Neurontin, A Clinical Update" in which the Medical Director promoted off-label uses of Neurontin to the doctors participating in the teleconference.

COUNT ONE: 21 U.S.C. §§ 331(d), 333(a)(2) & 355(a)

(Distribution of an Unapproved New Drug)

37. The allegations contained in paragraphs 1 through 36 are realleged and incorporated herein as if set forth in full.

38. Beginning as early as in or about April 1995, and continuing thereafter until at least in or about August 20, 1996, in the District of Massachusetts, and elsewhere,

WARNER-LAMBERT,

after previously having been convicted of violating the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331 and 333, did introduce and cause the introduction into interstate commerce from Puerto Rico and elsewhere, directly and indirectly, into Massachusetts and elsewhere, quantities of Neurontin, a drug within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(p), which drug was intended for use for the treatment of neuropathic pain, bipolar disorder, as monotherapy for epilepsy, and other Unapproved Uses. No approval, pursuant to 21 U.S.C. § 355, was in effect with respect to Neurontin for use in these conditions.

All in violation of 21 U.S.C. §§ 331(d), 333(a)(2), and 355(a).

COUNT TWO: 21 U.S.C. §§ 331(a), 333(a)(2) & 352(f)(1)

(Distribution of a Misbranded Drug: Inadequate Directions for Use)

39. The allegations contained in paragraphs 1 through 36 are realleged and incorporated herein as if set forth in full.

40. Beginning as early as April 1995, and continuing thereafter until at least in or about August 20, 1996, in the District of Massachusetts and elsewhere,

WARNER-LAMBERT,

after previously having been convicted of violating the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331 and 333, did introduce and cause the introduction into interstate commerce from Puerto Rico and elsewhere, directly and indirectly, into Massachusetts and elsewhere, quantities of Neurontin, a drug within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(p), which drug was intended for use for the treatment of neuropathic pain, bipolar disorder, as monotherapy for epilepsy, and other Unapproved Uses, and which was misbranded within the meaning of 21 U.S.C. § 352(a), in that Neurontin's labeling lacked adequate directions for such uses.

All in violation of 21 U.S.C. §§ 331(a), 333(a)(2), and 352(f)(1).

MICHAEL J. SULLIVAN
UNITED STATES ATTORNEY
DISTRICT OF MASSACHUSETTS

THOMAS E. KANWIT
ASSISTANT U.S. ATTORNEY

May 13, 2004

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DOS-1248 (1/08)

DEPARTMENT OF STATE
UNIFORM COMMERCIAL CODE
ONE COMMERCE PLAZA
99 WASHINGTON AVENUE
ALBANY, NY 12231-0001

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

ANN MONSUE, as Administratrix of the Estate of CLYDE MONSUE, Deceased, Plaintiff, - against - PFIZER INC., PARKE-DAVIS, a division of Warner-Lambert Company and Warner-Lambert Company LLC, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY LLC, EON LABS, INC., SANDOZ INC., and NOVARTIS PHARMACEUTICALS CORPORATION, Defendants.	Index No.: 150129/08 ANSWER

Defendants Pfizer Inc. ("Pfizer") and Warner-Lambert Company LLC, formerly known as Warner-Lambert Company ("Warner-Lambert"), on its own behalf and on behalf of its unincorporated division, Parke-Davis (collectively referred to hereinafter as "Defendants"), by their undersigned counsel, answer Plaintiff's Verified Complaint in the above-captioned action (the "Complaint") as follows:

AS TO STATEMENT OF THE CASE

1. Deny the allegations in paragraph 1, except admit that the United States Food and Drug Administration ("FDA") has approved Neurontin® ("Neurontin"), the brand name for gabapentin, for labeling as safe and effective only as adjunctive therapy in the treatment of partial seizures in patients with epilepsy and in the management of postherpetic neuralgia.

AS TO PARTIES AND JURISDICTION

2. Deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2, and therefore deny same.

3. Deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3, and therefore deny same.

4. Deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 4, and therefore deny same.

5. Admit the allegations in paragraph 5.

6. Admit the allegations in paragraph 6.

7. Admit the allegations in paragraph 7.

8. Deny the allegations in paragraph 8.

9. Deny the allegations in paragraph 9.

10. Deny the allegations in paragraph 10.

11. Deny the allegations in paragraph 11, except admit that Warner-Lambert Company was a Delaware corporation until December 31, 2002, when it was converted into a Delaware limited liability company, known as Warner-Lambert Company LLC.

12. Deny the allegations in paragraph 12, except admit that Warner-Lambert Company was authorized to do business in the State of New York until December 31, 2002.

13. Deny the allegations in paragraph 13, except admit that Warner-Lambert Company was a business entity actually doing business in the State of New York until December 31, 2002.

14. Deny the allegations in paragraph 14, except admit that Parke-Davis was a division of Warner-Lambert Company from approximately 1978 until approximately June 2000.

15. Deny the allegations in paragraph 15.

16. Deny the allegations in paragraph 16, except admit that from December 31, 2002 to the present Warner-Lambert Company LLC has been a Delaware limited liability company.

17. Deny the allegations in paragraph 17, except admit that Warner-Lambert Company LLC is a Delaware limited liability company authorized to do business in the State of New York since December 31, 2002.

18. Deny the allegations in paragraph 18, except admit that Warner-Lambert Company LLC has been a business entity actually doing business in the State of New York since December 31, 2002.

19. The allegations in paragraph 19 are directed at a defendant other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 19 and therefore deny same.

20. The allegations in paragraph 20 are directed at a defendant other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 20 and therefore deny same.

21. The allegations in paragraph 21 are directed at a defendant other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 21 and therefore deny same.

22. The allegations in paragraph 22 are directed at a defendant other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants

deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 22 and therefore deny same.

23. The allegations in paragraph 23 are directed at defendant other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 23 and therefore deny same.

24. The allegations in paragraph 24 are directed at defendant other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 24 and therefore deny same.

25. The allegations in paragraph 25 are directed at defendant other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 25 and therefore deny same.

26. The allegations in paragraph 26 are directed at defendant other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 26 and therefore deny same.

27. The allegations in paragraph 27 are directed at defendant other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 27 and therefore deny same.

28. Deny the allegations in paragraph 28, except admit that Pfizer is and has been the sole member of Warner-Lambert Company LLC since December 31, 2002.

29. Deny the allegations in paragraph 29.

30. Deny the allegations in paragraph 30.

31. Deny the allegations in paragraph 31.

32. Deny the allegations in paragraph 32, except admit that Warner-Lambert Company was a wholly-owned subsidiary of Pfizer from June 2000 through December 31, 2002.

33. Paragraph 33 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 33.

34. Deny the allegations in paragraph 34.

35. Deny the allegations in paragraph 35, except admit that Warner-Lambert Company LLC has been a wholly-owned subsidiary of Pfizer since December 31, 2002.

36. Paragraph 36 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 36.

37. Paragraph 37 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 37.

38. Paragraph 38 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 38.

39. Paragraph 39 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 39.

40. Paragraph 40 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 40.

41. Paragraph 41 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 41.

42. Paragraph 42 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 42.

43. Paragraph 43 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 43.

44. Paragraph 44 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 44.

45. Paragraph 45 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 45.

46. Paragraph 46 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 46.

47. Paragraph 47 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 47.

48. Paragraph 48 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 48.

49. Paragraph 49 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 49.

50. Paragraph 50 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 50.

51. Paragraph 51 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 51.

52. Paragraph 52 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 52.

53. Paragraph 53 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 53.

54. Paragraph 54 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 54.

55. Paragraph 55 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 55.

56. Paragraph 56 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 56.

57. Paragraph 57 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 57.

58. Paragraph 58 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 58.

59. Paragraph 59 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 59.

60. Paragraph 60 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 60.

61. Paragraph 61 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 61.

62. Paragraph 62 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 62.

63. Paragraph 63 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 63.

64. Paragraph 64 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 64.

65. Paragraph 65 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 65.

66. Paragraph 66 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 66.

67. Paragraph 67 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 67.

68. Paragraph 68 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 68.

69. Paragraph 69 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 69.

70. Paragraph 70 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 70.

71. Paragraph 71 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 71.

72. Paragraph 72 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 72.

73. Paragraph 73 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 73.

74. Paragraph 74 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 74.

75. Paragraph 75 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 75.

76. Paragraph 76 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 76.

77. Deny the allegations in paragraph 77, except admit that Pfizer's headquarters are in New York.

78. Paragraph 78 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 78.

79. Paragraph 79 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 79.

80. Paragraph 80 asserts a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 80.

81. The allegations in paragraph 81 are directed at defendants other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 81, and therefore deny same.

82. The allegations in paragraph 82 are directed at defendants other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 82, and therefore deny same.

83. The allegations in paragraph 83 are directed at defendants other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 83, and therefore deny same.

84. The allegations in paragraph 84 are directed at defendants other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 84, and therefore deny same.

85. The allegations in paragraph 85 are directed at defendants other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 85, and therefore deny same.

86. The allegations in paragraph 86 are directed at defendants other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 86, and therefore deny same.

87. The allegations in paragraph 87 are directed at defendants other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny the allegations in paragraph 87.

88. The allegations in paragraph 88 are directed at defendants other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny the allegations in paragraph 88.

89. Deny the allegations in paragraph 89, except admit that since June 2000, Pfizer, directly and/or indirectly through its subsidiaries, has marketed and sold Neurontin.

90. Deny the allegations in paragraph 90, except admit that Pfizer, directly and/or indirectly through its subsidiaries, has marketed and sold Neurontin since June 2000.

91. Deny the allegations in paragraph 91, except admit that Pfizer is engaged, directly and/or indirectly through its subsidiaries, in the business of designing, manufacturing, advertising, marketing and selling pharmaceutical drugs, and transacts business within the State of New York and contracts to provide goods in the State of New York.

92. Deny the allegations in paragraph 92.

93. Deny the allegations in paragraph 93.

94. Admit the allegations in paragraph 94.

95. Deny the allegations in paragraph 95.

96. Deny the allegations in paragraph 96.

97. Deny the allegations in paragraph 97, except admit that Parke-Davis marketed Neurontin on a date prior to May 29, 2007.

98. Deny the allegations in paragraph 98, except admit that Parke-Davis was a division of Warner-Lambert Company from approximately 1978 until approximately June 2000, and that until approximately June 2000, Parke-Davis directly and/or indirectly engaged in the business of marketing pharmaceutical drugs, including Neurontin, and transacted business within the State of New York and contracted to provide goods in the State of New York.

99. Deny the allegations in paragraph 99.

100. Deny the allegations in paragraph 100.

101. Deny the allegations in paragraph 101, except admit that Parke-Davis was a division of Warner-Lambert Company from approximately 1978 until June 2000 and that until June 2000, Parke-Davis directly or indirectly did and solicited business and engaged in a persistent course of conduct in the State of New York, deriving substantial revenue from goods and products consumed in the State of New York.

102. Deny the allegations in paragraph 102.

103. Deny the allegations in paragraph 103.

104. Deny the allegations in paragraph 104, except admit that Warner-Lambert Company marketed and sold Neurontin until June 2000.

105. Deny the allegations in paragraph 105, except admit that until December 31, 2002, Warner-Lambert Company was, directly and/or indirectly, engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs and transacted business within the State of New York and contracted to provide goods in the State of New York.

106. Deny the allegations in paragraph 106.

107. Deny the allegations in paragraph 107.

108. Deny the allegations in paragraph 108, except admit that until June 2000, Warner-Lambert Company, directly and/or indirectly, did and solicited business and engaged in a persistent course of conduct in the State of New York, deriving substantial revenue from goods and products consumed in the State of New York.

109. Deny the allegations in paragraph 109.

110. Deny the allegations in paragraph 110.

111. Deny the allegations in paragraph 111.

112. Deny the allegations in paragraph 112.

113. Deny the allegations in paragraph 113.

114. Deny the allegations in paragraph 114.

115. Deny the allegations in paragraph 115, except admit that since December 31, 2002, Warner-Lambert Company LLC has done and solicited business and engaged in a persistent course of conduct in the State of New York, deriving substantial revenue from goods and products consumed in the State of New York.

116. Deny the allegations in paragraph 116, except admit that since December 31, 2002, Warner-Lambert Company LLC has done and solicited business and engaged in a persistent course of conduct in the State of New York, deriving substantial revenue from interstate commerce.

117. The allegations in paragraph 117 are directed at a defendant other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 117, and therefore deny same.

118. The allegations in paragraph 118 are directed at a defendant other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 118, and therefore deny same.

119. The allegations in paragraph 119 are directed at a defendant other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 119, and therefore deny same.

120. The allegations in paragraph 120 are directed at a defendant other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny the allegations in paragraph 120.

121. The allegations in paragraph 121 are directed at a defendant other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny the allegations in paragraph 121.

122. The allegations in paragraph 122 are directed at a defendant other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 122, and therefore deny same.

123. The allegations in paragraph 123 are directed at a defendant other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 123, and therefore deny same.

124. The allegations in paragraph 124 are directed at a defendant other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 124, and therefore deny same.

125. The allegations in paragraph 125 are directed at a defendant other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 125, and therefore deny same.

126. The allegations in paragraph 126 are directed at a defendant other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 126, and therefore deny same.

127. The allegations in paragraph 127 are directed at a defendant other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny the allegations in paragraph 127.

128. The allegations in paragraph 128 are directed at a defendant other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny the allegations in paragraph 128.

129. The allegations in paragraph 129 are directed at a defendant other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 129, and therefore deny same.

130. The allegations in paragraph 130 are directed at a defendant other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 130, and therefore deny same.

131. The allegations in paragraph 131 are directed at a defendant other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 131, and therefore deny same.

132. The allegations in paragraph 132 are directed at a defendant other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 132, and therefore deny same.

133. The allegations in paragraph 133 are directed at a defendant other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 133, and therefore deny same.

134. The allegations in paragraph 134 are directed at a defendant other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny the allegations in paragraph 134.

135. The allegations in paragraph 135 are directed at a defendant other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny the allegations in paragraph 135.

136. The allegations in paragraph 136 are directed at a defendant other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 136, and therefore deny same.

137. The allegations in paragraph 137 are directed at a defendant other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 137, and therefore deny same.

AS TO BACKGROUND

138. Paragraph 138 does not allege facts to which a response is required, and Defendants therefore deny the allegations in paragraph 138.

139. Paragraph 139 does not allege facts to which a response is required, but to the extent that a response might be deemed required, Defendants admit the allegations in paragraph 139.

140. Paragraph 140 does not allege facts to which a response is required, and Defendants therefore deny the allegations in paragraph 140.

141. Paragraph 141 does not allege facts to which a response is required, and Defendants therefore deny the allegations in paragraph 141.

142. Paragraph 142 does not allege facts to which a response is required, and Defendants therefore deny the allegations in paragraph 142.

143. Paragraph 143 does not allege facts to which a response is required, and Defendants therefore deny the allegations in paragraph 143.

144. Deny the allegations in paragraph 144, except admit that, in 1993, the FDA approved Neurontin for labeling as safe and effective for adjunctive therapy in the treatment of partial seizures in patients with epilepsy at dosages of 900 to 1800 milligrams per day.

145. Deny the allegations in paragraph 145, except admit that the FDA has approved Neurontin for labeling as safe and effective only as adjunctive therapy in the treatment of partial seizures in patients with epilepsy and in the management of postherpetic neuralgia.

146. Deny the allegations in paragraph 146.

147. Deny the allegations in paragraph 147.

148. Deny the allegations in paragraph 148.

149. Deny the allegations in paragraph 149.

150. Deny the allegations in paragraph 150.

151. Deny the allegations in paragraph 151.

152. Deny the allegations in paragraph 152, except admit that Neurontin was approved as adjunctive therapy for the treatment of epilepsy.

153. Deny the allegations in paragraph 153.

154. Deny the allegations in paragraph 154.

155. Deny the allegations in paragraph 155, except admit that on May 13, 2004, an Information was filed against Warner-Lambert Company LLC in the United States District Court for the District of Massachusetts.

156. Deny the allegations in paragraph 156.

157. The allegations in paragraph 157 are directed at defendants other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 157, and therefore deny same.

158. The allegations in paragraph 158 are directed at defendants other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 158, and therefore deny same.

159. The allegations in paragraph 159 are directed at defendants other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants state that the federal laws and regulations governing generic prescription drugs speak for themselves.

160. The allegations in paragraph 160 are directed at defendants other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants state that the federal laws and regulations governing generic prescription drugs speak for themselves.

161. The allegations in paragraph 161 are directed at defendants other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants state that the federal laws and regulations governing generic prescription drugs speak for themselves.

162. The allegations in paragraph 162 are directed at defendants other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 162, and therefore deny same.

163. The allegations in paragraph 163 are directed at a defendant other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny the allegations in paragraph 163, except deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 163 regarding the Eon defendants' knowledge of Neurontin studies and off-label usage.

164. Deny the allegations in paragraph 164.

165. Deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 165, and therefore deny same.

166. Deny the allegations in paragraph 166, except deny knowledge or information sufficient to form a belief as to the truth of the allegations that Decedent's physician prescribed

Neurontin and/or gabapentin to treat Decedent's reflex sympathetic dystrophy, and therefore deny same.

167. Deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 167, and therefore deny same.

168. The allegations in paragraph 168 are directed at a defendant other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 168, and therefore deny same.

169. Deny the allegations in paragraph 169, except deny knowledge or information sufficient to form a belief as to the truth of the allegations that Decedent's physician prescribed Neurontin and/or gabapentin to treat Decedent's reflex sympathetic dystrophy, and therefore deny same.

170. Deny the allegations in paragraph 170.

171. Deny the allegations in paragraph 171.

172. Deny the allegations in paragraph 172.

173. Deny the allegations in paragraph 173.

174. To the extent the allegations in paragraph 174 are directed at a defendant other than Defendants, no response is required. To the extent the allegations in paragraph 174 are directed at Defendants, paragraph 174 asserts legal conclusions to which no response is required, and Defendants therefore deny the allegations in paragraph 174.

175. To the extent the allegations in paragraph 175 are directed at a defendant other than Defendants, no response is required. To the extent the allegations in paragraph 175 are directed at Defendants, Defendants deny the allegations in paragraph 175.

176. To the extent the allegations in paragraph 176 are directed at a defendant other than Defendants, no response is required. To the extent the allegations in paragraph 176 are directed at Defendants, Defendants deny the allegations in paragraph 176.

177. To the extent the allegations in paragraph 177 are directed at a defendant other than Defendants, no response is required. To the extent the allegations in paragraph 177 are directed at Defendants, Defendants deny the allegations in paragraph 177.

AS TO FIRST CAUSE OF ACTION

178. Repeat each and every response to the allegations in paragraphs 1 through 177.

179. Deny the allegations in paragraph 179.

180. Deny the allegations in paragraph 180.

181. Deny the allegations in paragraph 181.

182. Deny the allegations in paragraph 182.

183. Deny the allegations in paragraph 183.

184. Deny the allegations in paragraph 184.

185. Deny the allegations in paragraph 185.

186. Deny the allegations in paragraph 186, except admit that Plaintiff seeks the relief stated in paragraph 186, but deny that Plaintiff is entitled to such relief.

AS TO SECOND CAUSE OF ACTION

187. Repeat each and every response to the allegations in paragraphs 1 through 186.

188. Deny the allegations in paragraph 188.

189. Deny the allegations in paragraph 189.

190. Deny the allegations in paragraph 190.

191. Deny the allegations in paragraph 191.

192. Deny the allegations in paragraph 192.

193. Deny the allegations in paragraph 193.

194. Deny the allegations in paragraph 194, except admit that Plaintiff seeks the relief stated in paragraph 194, but deny that Plaintiff is entitled to such relief.

AS TO THIRD CAUSE OF ACTION

195. Repeat each and every response to the allegations in paragraphs 1 through 194.

196. Deny the allegations in paragraph 196.

197. Deny the allegations in paragraph 197.

198. Deny the allegations in paragraph 198.

199. Deny the allegations in paragraph 199, except admit that Plaintiff seeks the relief stated in paragraph 199, but deny that Plaintiff is entitled to such relief.

AS TO FOURTH CAUSE OF ACTION

200. Repeat each and every response to the allegations in paragraphs 1 through 199.

201. Deny the allegations in paragraph 201.

202. Deny the allegations in paragraph 202.

203. Deny the allegations in paragraph 203, except refer to the Information for its contents.

204. Deny the allegations in paragraph 204, except refer to the Information for its contents.

205. Deny the allegations in paragraph 205, except refer to the Information for its contents.

206. Deny the allegations in paragraph 206, except refer to the Information for its contents.

207. Deny the allegations in paragraph 207, except refer to the Information for its contents.

208. Deny the allegations in paragraph 208, except refer to the Information for its contents.

209. Deny the allegations in paragraph 209, except refer to the Information for its contents.

210. Deny the allegations in paragraph 210, except refer to the Information for its contents.

211. Deny the allegations in paragraph 211, except refer to the Information for its contents.

213.[1] Deny the allegations in paragraph 213, except refer to the Information for its contents.

214. Deny the allegations in paragraph 214, except refer to the Information for its contents.

215. Deny the allegations in paragraph 215, except refer to the Information for its contents.

216. Deny the allegations in paragraph 216, except refer to the Information for its contents.

217. Deny the allegations in paragraph 217, except refer to the Information for its contents.

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[1] Plaintiff's Complaint does not contain paragraph 212. For purposes of consistency, Defendants respond to Plaintiff's allegations as numbered in the Complaint.

218. Deny the allegations in paragraph 218, except refer to the Information for its contents.

219. Deny the allegations in paragraph 219 and all of its subparts, except refer to the Information for its contents.

220. Deny the allegations in paragraph 220, except refer to the Information for its contents.

221. Deny the allegations in paragraph 221, except refer to the Information for its contents.

222. Deny the allegations in paragraph 222, except refer to the Information for its contents.

223. Deny the allegations in paragraph 223, except refer to the Information for its contents.

224. Deny the allegations in paragraph 224, except refer to the Information for its contents.

225. Deny the allegations in paragraph 225, except refer to the Information for its contents.

226. Deny the allegations in paragraph 226, except refer to the Information for its contents.

227. Deny the allegations in paragraph 227, except refer to the Information for its contents.

228. Deny the allegations in paragraph 228, except refer to the Information for its contents.

229. Deny the allegations in paragraph 229, except refer to the Information for its contents.

230. Deny the allegations in paragraph 230.

231. Deny the allegations in paragraph 231.

232. Deny the allegations in paragraph 232.

233. Deny the allegations in paragraph 233.

234. Deny the allegations in paragraph 234, and all of its subparts.

235. Deny the allegations in paragraph 235.

236. Deny the allegations in paragraph 236.

237. Deny the allegations in paragraph 237.

238. Deny the allegations in paragraph 238.

239. Deny the allegations in paragraph 239.

211.[2] Deny the allegations in paragraph 211.

240. Deny the allegations in paragraph 240, except refer to the supplemental NDA and the letter dated August 26, 1997 referenced in paragraph 240 for their contents.

241. Deny the allegations in paragraph 241.

242. Deny the allegations in paragraph 242.

243. Deny the allegations in paragraph 243, except refer to the letter dated June 29, 2001 for its contents.

244. Deny the allegations in paragraph 244, except refer to the letter dated July 1, 2002 for its contents.

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[2] Plaintiff's Complaint incorrectly identifies paragraph 240 as paragraph 211. For purposes of consistency, Defendants respond to Plaintiff's allegations as numbered in the Complaint.

245. Deny the allegations in paragraph 245.

246. Deny the allegations in paragraph 246.

247. Deny the allegations in paragraph 247.

248. Deny the allegations in paragraph 248.

249. Deny the allegations in paragraph 249.

250. Deny the allegations in paragraph 250.

251. Deny the allegations in paragraph 251, except refer to the article referenced in paragraph 251 for its contents.

252. Deny the allegations in paragraph 252.

253. Deny the allegations in paragraph 253.

254. Deny the allegations in paragraph 254.

255. Deny the allegations in paragraph 255, except admit that sales of Neurontin have increased since 1999 and deny knowledge or information sufficient to form a belief as to the percentage of Neurontin prescribed for off-label uses.

256. Deny the allegations in paragraph 256.

257. Deny the allegations in paragraph 257.

258. Deny the allegations in paragraph 258.

259. Deny the allegations in paragraph 259.

260. Deny the allegations in paragraph 260.

261. Deny the allegations in paragraph 261, except admit that sales of Neurontin have increased since 1998, and deny knowledge or information sufficient to form a belief as to the percentage of Neurontin prescribed for off-label uses.

262. Deny the allegations in paragraph 262.

263. Deny the allegations in paragraph 263.

264. Deny the allegations in paragraph 264.

265. Deny the allegations in paragraph 265.

266. Deny the allegations in paragraph 266.

267. Deny the allegations in paragraph 267.

268. Deny the allegations in paragraph 268.

269. Deny the allegations in paragraph 269, except admit that Plaintiff seeks the relief stated in paragraph 269, but deny that Plaintiff is entitled to such relief.

AS TO FIFTH CAUSE OF ACTION

270. Repeat each and every response to the allegations in paragraphs 1 through 269.

271. Deny the allegations in paragraph 271.

272. Deny the allegations in paragraph 272.

273. Deny the allegations in paragraph 273, except admit that Plaintiff seeks the relief stated in paragraph 273, but deny that Plaintiff is entitled to such relief.

AS TO SIXTH CAUSE OF ACTION

274. Repeat each and every response to the allegations in paragraphs 1 through 273.

275. The allegations in paragraph 275 are directed at defendants other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny the allegations in paragraph 275.

276. The allegations in paragraph 276 are directed at defendants other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny the allegations in paragraph 276.

277. The allegations in paragraph 277 are directed at defendants other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny the allegations in paragraph 277.

278. The allegations in paragraph 278 are directed at defendants other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny the allegations in paragraph 278.

279. The allegations in paragraph 279 are directed at defendants other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny the allegations in paragraph 279.

280. The allegations in paragraph 280 are directed at defendants other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny the allegations in paragraph 280.

281. The allegations in paragraph 281 are directed at defendants other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny the allegations in paragraph 281, except admit that Plaintiff seeks the relief stated in paragraph 281, but deny that Plaintiff is entitled to such relief.

AS TO SEVENTH CAUSE OF ACTION

282. Repeat each and every response to the allegations in paragraphs 1 through 281.

283. The allegations in paragraph 283 are directed at defendants other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny the allegations in paragraph 283.

284. The allegations in paragraph 284 are directed at defendants other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny the allegations in paragraph 284.

285. The allegations in paragraph 285 are directed at defendants other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny the allegations in paragraph 285.

286. The allegations in paragraph 286 are directed at defendants other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny the allegations in paragraph 286.

287. The allegations in paragraph 287 are directed at defendants other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny the allegations in paragraph 287.

288. The allegations in paragraph 288 are directed at defendants other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny the allegations in paragraph 288.

289. Paragraph 289 is directed at a defendant other than the Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny the allegations in paragraph 289, except admit that Plaintiff seeks the relief stated in paragraph 289, but deny that Plaintiff is entitled to such relief.

AS TO EIGHTH CAUSE OF ACTION

290. Repeat each and every response to the allegations in paragraphs 1 through 289.

291. The allegations in paragraph 291 are directed at defendants other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny the allegations in paragraph 291.

292. The allegations in paragraph 292 are directed at defendants other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny the allegations in paragraph 292.

293. The allegations in paragraph 293 are directed at defendants other than Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny the allegations in paragraph 293.

294. Paragraph 294 is directed at defendants other than the Defendants and therefore no response is required. To the extent a response is deemed necessary, Defendants deny the allegations in paragraph 294, except admit that Plaintiff seeks the relief stated in paragraph 294, but deny that Plaintiff is entitled to such relief.

AS TO NINTH CAUSE OF ACTION

295. Repeat each and every response to the allegations in paragraphs 1 through 294.

296. To the extent the allegations in paragraph 296 are directed at a defendant other than Defendants, no response is required. To the extent the allegations in paragraph 296 are directed at Defendants, Defendants deny the allegations in paragraph 296.

297. To the extent the allegations in paragraph 297 are directed at a defendant other than Defendants, no response is required. To the extent the allegations in paragraph 297 are directed at Defendants, Defendants deny the allegations in paragraph 297.

298. To the extent the allegations in paragraph 298 are directed at a defendant other than Defendants, no response is required. To the extent the allegations in paragraph 298 are

directed at Defendants, Defendants deny the allegations in paragraph 298. Admit that Plaintiff seeks the relief set forth in the WHEREFORE paragraph following paragraph 298, and all of its subparts, but deny that Plaintiff is entitled to such relief.

GENERAL DENIAL

Defendants deny all allegations and/or legal conclusions set forth in the Complaint that have not previously been specifically admitted, denied, or explained.

AFFIRMATIVE DEFENSES

Without assuming the burden of proof of such defenses that they would not otherwise have, Defendants affirmatively assert the following defenses:

FIRST AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief may be granted.

SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States because Defendants' product is comprehensively regulated by the United States Food and Drug Administration ("FDA") pursuant to the Federal Food, Drug & Cosmetic Act, 21 U.S.C. §§ 301 et seq. ("FDCA"), and regulations promulgated thereunder, and Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should or should not be used in the labeling accompanying the drug.

THIRD AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, by the deference that common law gives to discretionary actions by FDA under the FDCA.

FOURTH AFFIRMATIVE DEFENSE

Plaintiff's claims may be barred, in whole or in part, under the doctrine of primary jurisdiction, in that the pertinent conduct of Defendants and all their activities with respect to the subject product have been and are conducted under the supervision of the FDA.

FIFTH AFFIRMATIVE DEFENSE

Plaintiff's Complaint is defective for failure to join indispensable parties.

SIXTH AFFIRMATIVE DEFENSE

The claims set forth in the Complaint are barred because Decedent's alleged injuries and damages, if any, were actually or proximately caused by the intervening or superseding conduct of persons or entities over which or whom Defendants had no control.

SEVENTH AFFIRMATIVE DEFENSE

Decedent's injuries and damages, if any, were due to idiosyncratic reactions to Neurontin for which Defendants cannot be held responsible.

EIGHTH AFFIRMATIVE DEFENSE

The claims set forth in the Complaint are barred because the alleged injuries and damages, if any, were caused by medical conditions or processes (whether pre-existing or contemporaneous) unrelated to Neurontin.

NINTH AFFIRMATIVE DEFENSE

The claims set forth in the Complaint are barred by the learned intermediary doctrine.

TENTH AFFIRMATIVE DEFENSE

The claims set forth in the Complaint are barred by the limitations on the doctrine of strict product liability for a purported design defect and breach of warranty as set forth in the Restatement Second of Torts, Section 402A, comment K.

ELEVENTH AFFIRMATIVE DEFENSE

To the extent Plaintiff claims a product defect, such claims are or may be barred by the doctrine described in Section 4 of the Restatement Third of Torts: Products Liability, because Defendants complied with applicable product safety statutes and administrative regulations. Neurontin, an FDA-approved prescription drug, was prepared and labeled in accordance with applicable statutes and regulations.

TWELFTH AFFIRMATIVE DEFENSE

To the extent Plaintiff claims a product defect, Plaintiff's claims are barred by the doctrines described in Sections 6(c) and (d) of the Restatement Third of Torts: Products Liability. Reasonable physicians knowing of the reasonably foreseeable risks and therapeutic benefits associated with Neurontin would have prescribed and did prescribe Neurontin for classes of patients. In addition, Defendants provided prescribing physicians with reasonable instructions or warnings regarding foreseeable risks of harm.

THIRTEENTH AFFIRMATIVE DEFENSE

To the extent Plaintiff claims a product defect, such claims are barred because, at the time the product left the control of Defendants, a practical and technically feasible alternative design or formulation was not available that would have prevented the alleged damages without substantially impairing the usefulness or intended purpose of the product.

FOURTEENTH AFFIRMATIVE DEFENSE

To the extent applicable, any recovery by Plaintiff must be reduced or offset by amounts Plaintiff has received or will receive from others for the same injuries claimed in this lawsuit.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred by the doctrines of release, accord, and satisfaction.

SIXTEENTH AFFIRMATIVE DEFENSE

The product may have been substantially modified and/or altered; therefore, Plaintiff's claims are barred.

SEVENTEENTH AFFIRMATIVE DEFENSE

The claims set forth in the Complaint are barred because the methods, standards and techniques used in formulating Neurontin and in issuing warnings and instructions about its use conformed to the generally recognized, reasonably available and reliable state of knowledge in the field at the time Neurontin was manufactured.

EIGHTEENTH AFFIRMATIVE DEFENSE

The claims set forth in the Complaint are barred because Decedent's alleged injuries and damages, if any, were caused by Decedent's misuse of Neurontin.

NINETEENTH AFFIRMATIVE DEFENSE

The claims set forth in the Complaint are barred because the foreseeable therapeutic benefits of Neurontin outweighed any foreseeable risks of harm.

TWENTIETH AFFIRMATIVE DEFENSE

To the extent applicable, the claims set forth in the Complaint are barred by the doctrine of informed consent and assumption of risk.

TWENTY-FIRST AFFIRMATIVE DEFENSE

The claims set forth in the Complaint are barred because Defendants breached no warranty, express or implied, to Decedent.

TWENTY-SECOND AFFIRMATIVE DEFENSE

The claims set forth in the Complaint are barred by the applicable statutes of limitation and/or repose.

TWENTY-THIRD AFFIRMATIVE DEFENSE

The claims set forth in the Complaint are barred under the doctrines of estoppel, waiver, ratification, laches and unclean hands and other related doctrines and principles, or any one of them, and by Plaintiff's inequitable conduct, lack of diligence, delay and inattention in pursuing such claims.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

To the extent applicable, Plaintiff's claims for damages are barred, in whole or part, by Plaintiff's and Decedent's failure to mitigate damages.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

To the extent applicable, Defendants specifically assert the defenses of comparative negligence and comparative assumption of risk.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

To the extent Tennessee law is deemed applicable, Defendants' liability for non-economic damages is several rather than joint and should be prorated.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

To the extent applicable, Defendants are entitled to contribution from any person and/or entity whose negligence or other fault contributed to Decedent's alleged injuries and damages.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

To the extent applicable, if Plaintiff and/or Plaintiff's Decedent suffered or sustained the loss, damage, injury, harm, expense, diminution, or deprivation alleged, which Defendants deny, the same was caused in whole or in part or was contributed to by the negligence of Plaintiff's Decedent.

TWENTY-NINTH AFFIRMATIVE DEFENSE

The Complaint fails to state facts sufficient to sustain a claim for, or recovery of, punitive or exemplary damages.

THIRTIETH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part by the First Amendment to the United States Constitution.

THIRTY-FIRST AFFIRMATIVE DEFENSE

Defendants affirmatively aver that the product at issue complied with all government standards as referred to in TENN. CODE ANN. § 29-28-104 and said product was not then at the time of manufacture and sale and is not now in an unreasonably dangerous condition in regard to matters covered by these standards and Defendants plead the Tennessee Products Liability Act of 1978, TENN. CODE ANN. § 29-28-101, et seq., in full bar of any liability on the part of Defendants.

THIRTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's fraud and consumer protection claims are barred by reason of the Complaint's failure to allege the factual circumstances constituting these specific claims with particularity.

THIRTY-THIRD AFFIRMATIVE DEFENSE

To the extent Plaintiff makes a claim for punitive damages or multiples of actual damages, Defendants assert that Plaintiff has not complied with federal or state statutory requirements to recover such damages.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

Any claims for punitive and exemplary damages or multiples of actual damages, are barred by the Fourth, Fifth, Sixth, Eighth, and Fourteenth Amendments to the United States Constitution and the law of Tennessee and/or other applicable state law.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

While Defendants deny that they are liable for any punitive and/or exemplary damages (hereinafter "such damages") in this case, to the extent Plaintiff claims such damages, they cannot be sustained because any award of such damages, which are penal in nature, without according to Defendants the same protections that are accorded to criminal defendants, including the protection against unreasonable searches and seizures, self-incrimination, and the right to confront adverse witnesses, a speedy trial, and the effective assistance of counsel, would violate Defendants' rights guaranteed by the Fourth, Fifth, Sixth, and Fourteenth Amendments to the United States Constitution and would also violate law of Tennessee and/or other applicable state law.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

With respect to Plaintiff's demand for punitive and exemplary damages, Defendants specifically incorporate by reference any and all standards or limitations regarding the determination and enforceability of punitive and exemplary damage awards which arose in the decisions of BMW of North America Inc. v. Gore, 517 U.S. 559 (1996), Cooper Industries, Inc. v. Leatherman Tool Group, 532 U.S. 424 (2001), State Farm Mut. Auto. Ins. Co. v. Campbell, 538 U.S. 408 (2003), and Philip Morris USA v. Williams, 127 S. Ct. 1057 (2007).

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiff's claims should be dismissed and/or transferred due to improper and/or inconvenient venue or forum pursuant to CPLR § 327.

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

To the extent Plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to Buckman Co. v. Plaintiff's Legal Committee, 531 U.S. 341 (2001).

THIRTY-NINTH AFFIRMATIVE DEFENSE

To the extent applicable, Plaintiff's claims for damages are barred, in whole or part, by the doctrines of res judicata (claim preclusion) and/or collateral estoppel (issue preclusion).

FORTIETH AFFIRMATIVE DEFENSE

Plaintiff's breach of warranty claims are barred because Plaintiff failed to give Defendants timely notice of those claims.

FORTY-FIRST AFFIRMATIVE DEFENSE

Any and all actions taken by Defendants with respect to any of the matters alleged in the Complaint were taken in good faith and in accordance with established industry practice.

FORTY-SECOND AFFIRMATIVE DEFENSE

To the extent applicable, Plaintiff's claims are barred because Defendants have complied with all applicable regulations of the federal and state governments.

FORTY-THIRD AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, because Defendants did not make any false statements to Plaintiff and/or Decedent.

FORTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff is not entitled to recovery against Defendants because the conduct alleged in the Complaint was not the proximate cause of any alleged loss suffered by the Plaintiff and/or Decedent.

FORTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff is barred from recovery because the representations and actions alleged by Plaintiff were not material, in that they were not likely to have affected the decisions or conduct of the Decedent, or to have caused the Decedent to have chosen differently, but for such alleged

representations or actions, and in that the alleged representations and actions were not likely to have misled the Decedent acting reasonably under the circumstances.

FORTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiff is precluded from recovery because the representations and actions alleged by Plaintiff were not intended to deceive the Decedent.

FORTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiff and/or the Decedent has not sustained any injury or damages compensable at law.

FORTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiff may not recover on the claims pleaded in the Complaint because the damages sought are too speculative and remote.

FORTY-NINTH AFFIRMATIVE DEFENSE

Defendants deny that Plaintiff has valid consumer protection claims under the laws of Tennessee, or any other State, Commonwealth or District whose laws are or later become relevant in the course of this litigation. However, if such claims are found to exist, Defendants plead all available defenses under the Acts.

FIFTIETH AFFIRMATIVE DEFENSE

To the extent applicable, Defendants' liability for non-economic damages is several rather than joint and should be prorated pursuant to CPLR § 1601.

FIFTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff lacks standing to bring this action.

FIFTY-SECOND AFFIRMATIVE DEFENSE

Defendants reserve the right to raise additional affirmative and other defenses as may be established by discovery and the evidence in this case. Defendants further reserve the right to amend their Answer and to add such counterclaims as may become necessary after reasonable opportunity for investigation and discovery.

DEMAND FOR TRIAL BY JURY

Defendants hereby demand trial by jury.

WHEREFORE, Defendants respectfully request that the Court:

1. Enter judgment in their favor on all claims alleged in the Complaint;

2. Award Defendants the costs, disbursements and reasonable attorneys' fees associated with these proceedings; and

3. Grant Defendants such other and further relief as the Court may deem just and proper.

Dated: New York, NY
July 25, 2008

Respectfully submitted,

SCHOEMAN, UPDIKE & KAUFMAN, LLP

By: 

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Attorneys for Defendants Pfizer Inc. and Warner-Lambert Company LLC

EXHIBIT B

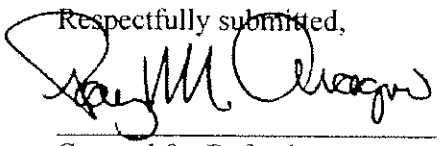
UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ANN MONSUE, as Administratrix of the Estate of CLYDE MONSUE, Deceased, Plaintiff, -against- PFIZER INC., PARKE-DAVIS, a division of Warner-Lambert Company and Warner-Lambert Company LLC, WARNER-LAMBERT COMPANY, WARNER LAMBERT COMPANY LLC, EON LABS, INC., SANDOZ INC. and NOVARTIS PHARMACEUTICALS CORPORATION, Defendants.	**Civil Action No.:** **(Removed from:** **Supreme Court State of New York,** **County of New York** **Index #: 08/150129)**

CONSENT TO REMOVAL

Defendant Eon Labs, Inc. hereby consents to the removal of this action from the Supreme Court of the State of New York, County of New York to this Honorable Court.

Respectfully submitted,



Counsel for Defendant
Eon Labs, Inc.
McKenna Long & Aldridge, LLP

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ANN MONSUE, as Administratrix of the Estate of CLYDE MONSUE, Deceased, Plaintiff, - against - PFIZER INC., PARKE-DAVIS, a division of Warner-Lambert Company and Warner-Lambert Company LLC, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY LLC, EON LABS, INC., SANDOZ INC., and NOVARTIS PHARMACEUTICALS CORPORATION, Defendants.	**Civil Action No.:**

CONSENT TO REMOVAL

Defendants Pfizer Inc. and Warner-Lambert Company LLC, formerly known as Warner-Lambert Company, on its own behalf and on behalf of its unincorporated division, Parke-Davis, hereby consent to removal of this action from the Supreme Court of the State of New York, County of New York, to the United States District Court for the Southern District of New York on the ground that the allegations in Plaintiff's Complaint raise substantial questions of federal law, and, therefore, federal subject matter jurisdiction exists pursuant to 28 U.S.C. § 1331. Defendant Pfizer Inc. was served with a summons and complaint in this matter on July 7, 2008.

Respectfully submitted,

William A. Alford III

William A. Alford III

Counsel for Defendants Pfizer Inc.
and Warner-Lambert Company LLC

EXHIBIT C

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Rockville MD 20857

DEC 24 1996

TO ALL ANDA AND AADA APPLICANTS

Dear Sir or Madam:

As part of the ongoing initiatives to reinvent government, the Office of Generic Drugs (OGD), like most other Federal programs, is faced with reduced resources. In addition to diminishing resources, OGD experienced a significant increase in submissions in late 1995. This higher level of submissions has continued in 1996. These combined factors resulted in an increased backlog of pending submissions. In order to help minimize the impact of these factors on review times, OGD began a series of internal meetings to identify procedures that would help streamline the review process. In addition, OGD believes these efforts will improve communications with industry and reduce the overall time to approval of abbreviated applications.

This letter describes the first streamlining initiatives that affect the chemistry, bioequivalence and labeling review processes. OGD looks forward to implementing additional streamlining initiatives in the future. The letter also contains an update on a variety of application related matters that will be of interest to applicants.

The Office trusts the information will be useful to you. Your cooperation in these matters will assist us in our effort to improve the efficiency of the generic drug review process.

Sincerely yours,

D. J. Sporn

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

INDEX

For ease in referencing the material contained in the letter, topics are presented in the following order at the specified pages:

REVIEW ISSUES

COMMUNICATING NOT APPROVABLE DETERMINATIONS

Effective January 1, 1997, the Office of Generic Drugs (OGD) will provide most application related "not approvable" deficiencies, both major and minor, to ANDA/AADA holders via facsimile for unapproved original applications. This is expected to decrease time to final action on applications. However, for the present time, the Division of Bioequivalence will continue to issue deficiency letters as it has always done.

The facsimile will include the usual components of a deficiency letter, but not in the traditional letter format. It will include:

A. A list of chemistry, manufacturing, and controls (CMC) deficiencies followed by additional CMC comments regarding status of methods validation, pre-approval inspection, and other related points.

B. A list of labeling deficiencies.

C. A list of microbiology deficiencies, if applicable.

A cover sheet will accompany the deficiency list which will provide instructions on how to respond to the facsimile.

To assist the Office in providing the facsimiles, applicants are requested to provide or update the facsimile number for its Regulatory Affairs contact person.

MAJOR NOT APPROVABLE DEFICIENCY PROCEDURES

Major CMC deficiencies identified by OGD will be sent to the applicant by facsimile. Responses from the applicant to these deficiencies will be regarded as a major amendment and should be submitted as an archival (hard) copy to OGD. OGD will not accept facsimile responses for major deficiencies.

MINOR NOT APPROVABLE DEFICIENCY PROCEDURES

For CMC deficiencies defined as minor, OGD will also communicate to the applicant by facsimile. The facsimile cover sheet that OGD sends to an applicant will identify the deficiency response as either a "Facsimile Amendment" or a "Minor Amendment". Procedures for responding to these two

types of amendments are as follows:

A. Facsimile Amendment

There will be some minor deficiencies for which OGD believes a complete response can be provided by the applicant within 30 days. These deficiencies will be provided by facsimile and will NOT stop the regulatory review clock.

The applicant will be asked to respond directly to OGD's document room by facsimile, followed with a hard copy. Facsimile amendments will be reviewed ahead of other priority or routine submissions pending in the reviewer's queue.

Should the complete response (facsimile and hard copy) not be received within 30 days, the applicant's response will be considered a minor amendment and placed into the reviewer's minor amendment queue.

B. Minor Amendment

There will be some minor amendments for which a response cannot be provided within 30 days. These will typically be for situations when the response is beyond the control of the applicant, e.g., Drug Master File (DMF) deficiencies. OGD will provide these deficiencies by facsimile and will STOP the regulatory review clock. In addition, the applicant's response (minor amendment) should be submitted as an archival(hard) copy to OGD and will be placed into the reviewer's queue according to OGD's first-in, first-reviewed policy. OGD will not accept facsimile responses for these minor amendments.

In order to evaluate the expected benefits of this new process, the Office will be monitoring the impact on action times. However, reports of industry experiences with this process are encouraged.

PHONE CONSULTATION FOLLOWING SECOND REVIEW CYCLE WITH MAJOR DEFICIENCIES

Applicants who find that an application continues to have major CMC deficiencies after the second review cycle are encouraged to call the appropriate Project Manager (PM) in OGD to discuss or clarify the deficiencies. Where appropriate the

PM will involve the chemistry reviewer and/or others in the discussion. The goal is to answer questions, assist the applicant to understand the identified deficiencies and, hopefully, eliminate further major deficiency reviews. In some cases meetings may be necessary to clarify these deficiencies. OGD will contact the applicant within approximately 30 days after issuance of the second major deficiency letter if the Office has not been contacted by the applicant. OGD will also use the same approach for subsequent reviews where major deficiencies remain.

Currently, OGD is unable to provide this level of service after the first review cycle due to the volume of such submissions and the Office's limited resources.

ALTERNATE DRUG SUBSTANCE FOR ORIGINAL APPLICATIONS

The Office of Generic Drugs has announced a change in policy regarding adding an alternate source of the new drug substance (NDS) to an original application prior to approval.

Previously, if an abbreviated application was otherwise approvable with the exception of an unsatisfactory inspection of Current Good Manufacturing Practices (cGMP) for the primary NDS supplier used to manufacture the exhibit/bioequivalence batch, it would not be approved until those cGMP issues were resolved. In order to qualify an acceptable alternate source of the NDS, a new exhibit batch based on the alternate source would be needed. Additionally, a bioequivalence study would be required (depending on dosage form) to support use of the alternate source.

For unapproved applications, OGD now allows substitution of an alternate source of the new drug substance based on assurance that the specifications and test data are essentially the same as those of the original source used in the exhibit batch (and bioequivalence study, if required) that would have been acceptable except for cGMP issues, etc. Additionally, the DMF must be found acceptable. Generally, a new *in vivo* bioequivalence study will not be required for the alternate exhibit batch, but it will be necessary to provide comparative dissolution data depending on the dosage form of the proposed product. This new policy is identical to the existing policy regarding post approval changes to provide for alternate sources of the NDS.

Note that there are some situations where this new policy would not apply and a new acceptable exhibit batch, an *in vivo* bioequivalence study, and comparative dissolution data would be required. This might be the case when there are significant differences in particle size or physicochemical

characteristics.

BIOEQUIVALENCE ISSUES

ELECTRONIC SUBMISSION PROJECT

Effective January 1, 1997, the Office of Generic Drugs will implement its program for electronic submission of bioequivalence data. The program was developed under contract with the University of Maryland (UM). Under the program, applicants that choose to, may prepare electronic submissions on diskette with the aid of a user-friendly program call Entry and Validation Program (EVA). EVA is free of charge to applicants through the UM's World Wide Web site (http://mundos.ifom.umbc.edu/~fdacom). The Web site also permits applicants to register as participants and to obtain updated information on the program including any new versions of EVA. Companies can also ask technical questions through the Web site, which will be addressed by UM staff.

The program is expected to have a very positive impact on the efficiency of reviews, ultimately reducing review times. In addition, it is hoped the program will help reduce the time required to reach approval. Therefore, OGD strongly encourages firms to participate.

For most companies, the time to start planning the electronic submission is before study data are prepared. For those using Contract Research Organizations (CROs) to conduct bioequivalence studies, applicants could specify in their requirements that the CROs prepare the data in the requested format. CROs are encouraged to access the UM Web site and to become familiar with EVA and submission requirements. Applicants may also make electronic submissions for applications already submitted to the Office, but should contact the Bioequivalence Project Manager (Ms. Lizzie Sanchez, 301-594-2290) first, to make certain the electronic submission will be received in time for the review.

We hope to conduct training for applicants in conjunction with UM. Those applicants interested in such training are encouraged to register their interest through the UM Web site. Technical questions about the program may be addressed to the UM at 410-455-3888 or through the UM Web site. Regulatory questions may be addressed to the Bioequivalence Project Manager.

The electronic submission program is part of a larger strategy for Electronic Regulatory Submission and Review (ERSR) which will soon include the chemistry, manufacturing, and controls (CMC) portion of generic drug applications.

AVAILABILITY OF BIOEQUIVALENCE PROTOCOL REVIEWS

Firms frequently submit proposed *in vivo* bioequivalence study protocols to OGD. Often these are duplicative of already submitted and reviewed protocols. In order to decrease the burden of reviewing several protocols for the same drug product, OGD is now making available copies of acceptable protocols and related review comments. OGD believes that by utilizing completed review comments, firms will need to submit fewer protocols, freeing time for evaluation of applications. Copies may be obtained from the Drug Information Branch, HFD-210, Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD, 20857. The current phone number for the Drug Information Branch is (301) 827-4573. Please note that this number was recently changed because that branch re-located.

The list of protocols available may be accessed through "FAX on Demand" at (800) 342-2722 or (301) 827-0577. You are encouraged to obtain an updated list by this means. However, the Division of Bioequivalence will also maintain a listing.

There are caveats to be borne in mind regarding this new resource:

A. *The material available will be redacted protocols and letters transmitting the review comments.*

B. *It will take some time to prepare protocols and reviews for distribution through this process. Therefore, the number of different product protocols and review will gradually increase, over time.*

C. *The procedure is new and may require fine tuning. Thus, comments and suggestions are encouraged. These may be submitted to Ms. Lissie Sanchez at (301) 594-2290.*

C. *There will be a transition period during which firms with pending requests for protocol review may be contacted regarding the imminent availability of a review of another protocol regarding the product for which they had submitted a protocol. The firm may wish to withdraw its protocol and use information available from the previously acceptable review.*

Please note that though this service is available, the Division may be contacted should there appear to be circumstances necessitating review of another protocol for the

same drug product.

UPDATE ON ALBUTEROL INHALATION AEROSOL GUIDANCE

On January 27, 1994, OGD issued the guidance titled "Interim Guidance for Documentation of *in vivo* Bioequivalence of Albuterol Inhalation Aerosols (Metered Dose Inhalers)." Since its publication, the Office has had the opportunity to review additional information on various aspects of *in vivo* and *in vitro* testing conducted as described in the guidance and has concluded that a revision of the guidance is needed. A CDER working group developed recommendations for revision and presented them to a joint session of the Advisory Committee for Pharmaceutical Science (ACPS) (a re-configuration of the Generic Drugs Advisory Committee - GDAC) and the Pulmonary Drugs Advisory Committee in August of 1996.

Therefore, should studies for albuterol metered dose inhalers (MDI s) be under consideration, sponsors are strongly encouraged to wait for the revised guidance, or, in the interim, discuss their planned study with the Division of Bioequivalence. The guidance will be developed as expeditiously as possible and the industry will be informed of its availability.

BIOEQUIVALENCE STUDIES TO BE CONDUCTED IN APPROPRIATE SUBJECTS

Though it is preferable to conduct bioequivalence testing in normal healthy volunteers, there are certain products for which use in healthy persons might be an unacceptable risk.

A. Cytotoxic drugs

Certain conditions and considerations regarding bioequivalence studies of cytotoxic drugs need to be specified. Please note the following:

21 CFR 320.31(a)(3) requires that any person planning to conduct an in vivo bioavailability or bioequivalence study in humans shall submit an investigational new drug application (IND). An IND provides assurance that studies proposed will have adequate safeguards for the safety of the subjects.

It is therefore recommended that studies with the following products be conducted in the appropriate patient population. Note also that the listing (developed in conjunction with the Division of Oncologic Drug Products) is subject to updating and revision. Consultation with the Office is recommended if any questions arise.

Bisulfan
Cyclophosphamide
Hexamethylmelamine
Melphalan
Procarbazine
Uracil Mustard
Tetramustine Phocphate
Chlorambucil
Etoposide
Lomustine
Pipobroman
Thioguanine
Methoxsalen

B. Ipratroprium

In order to fully evaluate the bioequivalence of this product, studies should be conducted in the appropriate patient population.

IN VIVO STUDIES UNDER SUPAC-IR

Under the Center's Guidance for Industry: Immediate Release Solid Oral Dosage Forms (SUPAC-IR) there are two types of post-approval changes for which *in vivo* bioequivalence testing is requested: Level 3 changes in components and composition as well as Level 3 manufacturing process changes. For generic drugs, the *in vivo* bioequivalence test should always compare the product after a post-approval change against the reference listed drug. However, in instances when a bioequivalence study is not necessary, dissolution studies should compare the applicant's generic product after a post-approval change against the same product prior to the change.

If there are any questions in regard to a reference product, please contact the Division of Bioequivalence for advice.

LABELING REVIEW CHANGES

The abbreviated application regulations require that side-by-side labeling comparisons be included with the submission of the original, unapproved application, with all differences between the proposed ANDA/AADA and the reference listed drug (RLD) labeling annotated and fully explained [See 21 CFR 314.94(a)(8)]. Side-by-side comparisons enable reviewers to readily identify differences between the ANDA/AADA and the reference listed drug labeling and/or the previous version of the applicant's labels and labeling.

OGD is now requesting a side-by-side comparison for all labeling changes submitted, not only in original applications, but also for all amendments and supplements. This comparison will help reduce the time required to review each new version of proposed labeling.

Additional actions to streamline the labeling review process have resulted in the following changes:

A. OGD will provide pen and ink comments directly on a applicant's proposed labeling and attach those comments to the Not Approvable facsimile. This will eliminate the time consuming task of identifying where in the labeling changes should be made and explaining the needed changes in letter format. This will conserve reviewer's time, thus making more efficient use of OGD resources.

B. Effective immediately, when changes are needed in labeling because of changes in the RLD labeling, OGD will either identify the specific changes to be made or will provide a copy of the most recently approved labeling of the RLD. In the past when MAJOR changes were required in the labeling, the applicant was required to obtain a copy of the cited approved labeling from the Freedom of Information (FOI) staff, then submit a supplement or amendment. This process added 4 to 6 weeks to the process of updating the ANDA/AADA labeling.

Please note that OGD will NOT supply labeling of the RLD BEFORE an application is filed. The most recent APPROVED labeling should be obtained from the FOI staff prior to preparation and submission of the labeling in an ANDA/AADA.

The Division of Labeling and Program Support highly recommends that ANDA/AADA applicants NOT utilize the Physician's Desk Reference (PDR) as the source for the most recently approved labeling of the innovator's product. Although the PDR may represent labeling that is available in the marketplace, some of this labeling may have been submitted to the Agency as a "Special Supplement - Changes Being Effected" (SSCBE). As such, it would have been implemented prior to FDA approval in accordance with 21 CFR 314.70(c). The FDA must still review, possibly recommend changes and approve the labeling before it is acceptable for use as model labeling for an ANDA/AADA product. In addition, other changes may have been made in the approved labeling after the publication of the PDR.

APPLICATION PROCESS ISSUES

Refusal to File Issues

The office evaluates abbreviated applications for completeness and acceptability prior to filing them for review. OGD has identified many issues which previously would have resulted in refuse to file determinations which can be easily resolved by applicants. These are now communicated by OGD by telephone

rather than issuing a letter which can take weeks. Such items include:

No cGMP statement
FDA Form 356h does not contain an original signature
Improper patent certification
Exclusivity rights not addressed
No debarment/list of convictions statement
No certification of field copy
Need for additional copies of labeling

Applicants are given 10 working days to respond. If a response is not received in that time, a refuse to file letter is issued.

This approach has resulted in a decrease in refuse to file determinations and moves applications into the review queue more rapidly. Even with this approach, the refuse to file rate for applications remains high. Therefore, an update of the key reasons the Office refuses to file abbreviated applications follows:

A. DMF Issues

No authorization for the Drug Master File (DMF) or incomplete information about the DMF.

The DMF authorization must be from the DMF holder or its U.S. agent to permit the agency to refer to the DMF on behalf of the applicant. If the authorization is from the agent, an additional letter of appointment of the agent must also be included from the holder of the DMF (link to DMF holder). The authorization for the agency to refer to the DMF must reference the specific applicant, not another corporate entity related to the applicant.

For further information please refer to the CDER Guideline for Drug Master Files.

B. Inactive Ingredient Issues

Inadequate information on the characterization of inactive ingredients.

The regulations related to parenteral, ophthalmic, otic and topical dosage forms [21 CFR 314.94(a)(9)] state that applicants shall identify and characterize the inactive ingredients in the proposed drug product and provide information

demonstrating that the inactive ingredients do not affect the safety of the proposed drug product. Additionally, OGD's Interim Inactive Ingredients Policy dated November 17, 1994, address inactive ingredient issues in more detail. The Interim Inactive Ingredient Policy is available in the OGD Docket (No. 9050308).

Thus, applicants should demonstrate that the proposed drug product is qualitatively and quantitatively the same as the reference listed drug product for parenteral, ophthalmic, otic, and topical dosage forms. An applicant may seek approval of a drug product that differs from the RLD, in certain instances, as described in the regulations.

Generally, products for oral inhalation are considered topical products. Therefore, applicants for these products are requested to provide a qualitative and quantitative comparison. Please refer to the Interim Inactive Ingredient Policy for further guidance.

For other topical products, i.e., creams, lotions, gels, suspensions, and solutions an applicant is requested to provide the following information:

1. Qualitative Statement

   A list of ingredients (test drug and reference drug) to show a qualitative comparison.

2. Quantitative Statement

   The quantitative composition of the test drug and the results of analysis of the reference drug. It may not be possible to accurately analyze some inactive ingredients contained in the reference product. However, applicants should make their best efforts to quantitatively analyze the ingredients in the reference drug and submit the results in the application. If an ingredient cannot be analyzed, or if results are irrelevant or inconclusive, an explanation should be provided. Sponsors may use the Center for Drug Evaluation and Research Inactive Ingredient Guide (IIG) as a reference for safe maximum levels. If the ingredient levels are not listed, the sponsor may also refer to

other sources of information, such as other approved topical products where quantitative levels are known, recognized literature references or information from the ingredient manufacturer.

OGD does not require a quantitative or qualitative analysis beyond the normal analytical capabilities within the industry.

If applicants have questions regarding inactive ingredients, they may submit a request for the opinion of the OGD on the acceptability of inactive ingredients prior to the submission of an application. The office can provide certain information in response to such requests.

C. Exclusivity Issues

Exclusivity right(s) or patent(s) not addressed.

Patents and exclusivity must be addressed. When there is no exclusivity or patent listed in the Orange Book, the applicant should provide a statement to this effect. It is also suggested that applicants verify they are using a current edition of the Orange Book and/or cumulative supplement as the basis for this information.

D. Packaging Information

No record of or incomplete packaging information on the exhibit batch.

This packaging information is requested in order for the application to be filed. This request is outlined in OGD's Policy and Procedure Guide #41-93.

ACCEPTANCE OF ANDA BASED ON A PENDING PETITION FOR A DETERMINATION OF REASONS FOR VOLUNTARY WITHDRAWAL OF THE REFERENCE LISTED DRUG

OGD can accept an Abbreviated New Drug Application that refers to a listed drug that has been voluntarily withdrawn from sales as long as the applicant provides evidence that a Citizen's Petition has been submitted to request a determination of whether a listed drug has been voluntarily withdrawn for safety or efficacy reasons. A Center response to that petition is not required for filing purposes. However, the Center must have made its determination on

relisting prior to the approval of the ANDA. (See 21 CFR 314.161 and 314.122)

DOCUMENTATION OF APPROPRIATE AUTHORIZATION OF AGENTS

It is acknowledged that there are many circumstances that require applicants to have other parties interact with the OGD on their behalf relative to specific applications. Frequently, written authorization for these agents is not contained in an application when submitted. The Office wishes to be cooperative in its response to applicant needs but must assure submitted material remains confidential and is not released or discussed with unauthorized individuals.

In order to allow for prompt responses, it is requested that written authorization be submitted to the application when filed or well before contact by an authorized agent is expected. Examples of who requires such authorization include:

A. The U.S. agent of a foreign firm.

B. A consultant to the firm that is expected to interact directly with OGD.

C. Legal counsel to the firm on issues that may necessitate direct interaction with OGD.

INFORMATION FOR INSPECTIONS

United States agents for foreign establishments are very helpful to the Office of Compliance in assigning foreign inspections. It is, therefore, important that complete information (name, address, phone/fax numbers) of the U.S. agent be included in an application.

Central File Numbers (CFN) as identifiers for facilities are also of value in the scheduling of inspections. Please provide these numbers for all facilities included in the application. CFN's are obtained by applying for them through the FDA District Offices.

OTHER

WITHDRAWAL OF APPLICATIONS

The Office requests that firms make periodic internal assessments and withdraw pending applications they may not wish to pursue to approval. This action will allow conservation of OGD's information tracking and document control resources.

It has been noted, as well, that there are many approved applications that have been discontinued from marketing. As long as these products are not formally withdrawn, applicants must continue to prepare and submit annual reports and adverse drug experience reports (See 21 CFR 314.120 and 314.81). Accordingly, OGD must process these reports, putting additional strain on its limited resources. We are requesting that such discontinued applications be voluntarily withdrawn. This action, of course, does not prejudice any re-filing of applications.

For any issue or clarification regarding the application process, applicants are strongly encouraged to contact a project manager in the Review Support Branch at (301) 594-0315 for assistance.

NEW PLASTIC CONTAINER SUBMITTED IN AN ABBREVIATED APPLICATION

Recently, CDER articulated its policy for applications for parenteral products in plastic immediate containers in a CDER Manual of Policies and Procedures (MAPP 6020.2). This policy applies to both large and small volume parenteral products. It also applies to applications for parenteral products packaged in plastic immediate containers regardless of whether the plastic material has been previously used to package an approved drug product.

21 CFR 310.509(a) established that any parenteral drug product packaged in a plastic immediate container is a new drug under section 201(p) of the Federal Food, Drug and Cosmetic Act (FD&C Act) and requires an approved new drug application (NDA) as a condition for marketing. Section 310.509 took effect when 505(b) was the only provision in the FD&C Act for submission of an NDA. The subsequent enactment of the Drug Price Competition and Patent Term Restoration Act of 1984 (Waxman-Hatch Amendments) replaced 505(b) with 505(b)(1), 505(b)(2) and 505(j), thereby creating three distinct types of applications for approval of new drugs depending on the nature and the source of the evidence required to demonstrate the safety and effectiveness of the new drug product.

CDER has determined that an application for approval of a parenteral product in a plastic immediate container may be filed as an ANDA under section 505(j) or, for antibiotics, an AADA under section 507, provided that the product duplicates an approved product listed in the current edition of the Orange Book and approval of the product in the plastic immediate container does not require studies beyond limited confirmatory testing, i.e., simple studies intended to rule out unlikely problems, and the testing described in the USP.

An application for approval of a parenteral product in a plastic immediate container for which the container requires animal studies beyond limited confirmatory testing and the testing described in the USP to show that the drug product is safe must be submitted as an NDA under section 505(b) or, for antibiotics, under section 507.

An application for approval of a parenteral product in a plastic immediate container containing an active ingredient or a combination of active ingredients not previously approved should be filed as an NDA.

CONTROLLED DOCUMENTS

In an attempt to assure consistent and timely responses to written inquiries from industry and other interested parties, OGD has established a controlled document tracking system. Written requests for information, opinions, and clarification of policy that do not pertain to an ANDA or AADA review (e.g., amendments, supplements) are considered "controlled documents" upon receipt. Written requests from individual firms to meet with OGD on application related topics as well as any other topics are also considered controlled correspondence. The incoming correspondence is assigned a "control number" and tracked within OGD until a response, either written or by telephone, is provided to the requestor.

In order to assure that a submission not related to an application is placed in the control document tracking system appropriately, please submit your request to the following address (instead of the Document Control Room):

Office of Generic Drugs, HFD-600
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 286
Rockville, MD 20855-2773

Please note, however that bioequivalence protocols should continue to be sent to the Division of Bioequivalence. Also, be aware that OGD will not conduct pre-reviews of applications, amendments, or similar documents via this mechanism.

EXHIBIT D

May 17, 2004

Food and Drug Administration
Dockets Management Branch
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Citizen Petition to Request Addition of Postmarketing Suicide Reports to the Neurontin (Pfizer/Parke-Davis) Labeling

Dear Sir/Madam,

Pursuant to 21 CFR 10.30, the enclosed Citizen Petition has been prepared to request the amplification of the current Neurontin labeling to properly reflect the significant number of postmarketing reports of completed suicides, suicidal attempts and suicidal ideations. The current Neurontin labeling provides no information relating to these postmarketing reports in the section entitled Postmarketing and Other Experience. The enclosed submission includes three copies of the Citizen Petition.

Please contact the undersigned if you have any questions or require additional information.

Very Truly Yours,

Keith Altman

Keith Altman
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2004P-0235

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THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION

May 17, 2004

Petition to Require Pfizer, Inc. (and its Subsidiaries Including Parke-Davis and The Warner-Lambert Co.) to Revise the Labeling of Neurontin® and Add Warnings, Precautions, and Adverse Event Information Relating to the Escalating Numbers of Postmarketing Reports of Completed Suicides and other Suicide-Related Events	**Docket No.** _____

Submitted by: **Keith Altman**
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CITIZEN PETITION

Keith Altman and Finkelstein and Partners submit this petition to request action by the Food and Drug Administration (FDA) relating to the drug product, Neurontin (gabapentin). The petitioners request that FDA require the manufacturer of Neurontin, Pfizer, Inc. and its subsidiaries including Parke-Davis and the Warner Lambert Co. (Pfizer) to amplify the Neurontin labeling to specifically warn prescribers and health care professionals of the escalating number of postmarketing reports of completed suicides by patients receiving Neurontin for both its labeled and unlabeled indications. The proposed actions include the addition of a Black Box Warning, amplified Precautions and Adverse Event information and dissemination of "Dear Doctor" and "Dear Healthcare Professional" letters. This Petition is submitted pursuant to 21 CFR 10.35, and relating to 21 CFR 201.5, 201.128, and Sections 201(n), 502(a), 502(f)(l) and 505 of the Federal Food, Drug and Cosmetic Act.

I. Introduction and Action Requested

Pfizer, Inc. manufactures and markets oral dosage forms of Neurontin (gabapentin). The current FDA approved labeling for Neurontin provides for its use in patients with Postherpetic Neuralgia and Epilepsy. However, recent reports have noted that a large percentage (approximately 80-90%) of Neurontin's U.S. sales is actually derived from sales for non-FDA approved uses. Pfizer has recently agreed to plead guilty to criminal wrongdoing in their illegal marketing practices designed to promote these unapproved uses. Neurontin enjoys wide use in the U.S. with annual sales exceeding two billion dollars.

The current FDA-approved labeling does not warn prescribers and patients to the increasing dangers of completed suicide and suicide-related events associated with Neurontin, as evidenced by the escalating numbers of postmarketing reports. For example, the current labeling provides no information to warn of completed suicides, although FDA's postmarketing Adverse Event Reporting System (A.E.R.S) database recorded a substantial increase in these fatalities during the first six months of 2003. Eight completed suicides were reported from 1998 through 2002. Seventeen additional suicides have been recorded for the period between January – June, 2003.

The petitioners request that the FDA Commissioner act immediately to require the labeling additions noted below. This action is especially critical because of Neurontin's wide use for nonlabeled indications and for which proper medical monitoring instructions have not been established by FDA.

- **Bolded Black Box Warning:**

Psychiatric Disorders
Neurontin has been associated with completed suicides, suicide attempts and suicidal ideations, in postmarketing reports. Prescribers should carefully monitor patients prior to initiation of Neurontin therapy and throughout its period of use. (See Precautions and Adverse Reactions)

- **PRECAUTIONS**

Suicide-Related Events:
Neurontin use has been associated with completed suicides, suicide attempts and suicidal ideations in postmarketing reports. Patients should be prospectively cautioned regarding the possibility of these events and advised to report any symptomatology immediately. Patients should also be carefully observed throughout therapy for signs of suicide-related symptoms.

- **ADVERSE REACTIONS (addition to existing section)**

Postmarketing and Other Experience:
"In the postmarketing period, there have been multiple reports of completed suicides, suicide attempts and suicidal ideations in patients receiving Neurontin for a variety of uses" (continuation of existing text).

- **Dear Doctor and Dear Healthcare Professional Letters**

The Petitioners believe the gravity of the reported events of completed suicides dictate health care providers be alerted to this information as soon as possible. These letters should be provided to all U.S. prescribers because of the high use of Neurontin for unlabeled indications encompassing several disciplines of medicine. Letters should also be sent to pharmacists, medical associations and hospitals to allow the most rapid and most extensive dissemination of this critical safety information. These letters should also provide guidance to prescribers in the proper screening of potential patients for the use of Neurontin. Advice should also be given to prescribers for the monitoring of suicide-related events in patients following the initiation of Neurontin and throughout its period of use.

II. Statement of Factual Grounds

A. The Current Neurontin Labeling Fails to Comply with Labeling Requirements

Under Sections 201(n), 502(a), 502(F)(1), and 505 of the Federal Food, Drug and Cosmetic Act and 21 CFR Sections 201.5 and 201.128, it is mandated that prescription drug product labeling must include all materials and facts necessary for their safe and effective use and must not be false and misleading in any particular including the failure to state material facts.

The current Neurontin labeling is provided with Attachment 1. This labeling does not address, in any manner, the postmarketing reports of completed suicides, suicide attempts and suicidal ideations. As such, the current labeling violates the applicable regulations by failure to state material facts. The Neurontin labeling does note that suicide gestures were rarely reported in the Neurontin premarketing clinical trials and that suicidal(*sic*) was infrequently reported in the clinical trials. It is important to note that completed suicides are not included, in any manner, in the Neurontin labeling. Pfizer acknowledges that postmarketing reports of completed suicides are currently unlabeled events when providing these as expedited reports to FDA's A.E.R.S. database (Attachment 2).

Given the recent sharp increase in the number of completed suicides reported in 2003, and the continued reporting of postmarketing attempted suicides and suicidal ideations, it is imperative that this postmarketing information be included in the Neurontin professional labeling as quickly as possible. Pfizer recognizes the need to emphasize postmarketing experience because the current Neurontin labeling includes a specific section for postmarketing experience. This information currently alerts prescribers to the following events: angioedema, blood glucose fluctuation, erythema multiforme, elevated liver function tests, fever, hyponatremia, jaundice, movement disorder such as dyskinesia and Stevens-Johnson syndrome. Obviously, it is as important for prescribers and patients to be made aware of increasing numbers of completed suicides, as it is to possible changes in clinical laboratory parameters.

B. The FDA's A.E.R.S. Database Indicates an Escalating Number of Completed Suicides, Suicide Attempts and Suicidal Ideations Received by Pfizer and FDA.

The Petitioners have evaluated FDA's A.E.R.S. database (provided by N.T.I.S.) and have summarized, below, the number of suicide-related events reported by Pfizer and others to FDA for the period 1998-2003. To date,

only the events reported for the first six months of 2003 have been released by FDA.

The following Tables provide both the number of events reported by Pfizer to FDA (Pfizer Count) and the total number of events received by FDA (Total Count). Because of the possibility of duplicate reports submitted by multiple manufacturers to FDA, the Petitioners will focus on the reports prepared and submitted by Pfizer. The suicide related events include the Preferred Terms of completed suicide, suicide attempt and suicidal ideation. The listed events adopt FDA's procedures and include the "last best case" data in order to consider the data from the latest follow-up of an individual report. If there are no follow-up reports, then the initial report data are used. The drug names employed in the search procedure were Neurontin and gabapentin.

Petitioners' Summary of Neurontin A.E.R.S. Events

Table 1. Completed Suicides

Preferred Term	Date	Total Count	Pfizer Count
COMPLETED SUICIDE	1998Q1	0	0
COMPLETED SUICIDE	1998Q2	0	0
COMPLETED SUICIDE	1998Q3	0	0
COMPLETED SUICIDE	1998Q4	0	0
COMPLETED SUICIDE	1999Q1	1	0
COMPLETED SUICIDE	1999Q2	0	0
COMPLETED SUICIDE	1999Q3	2	0
COMPLETED SUICIDE	1999Q4	0	0
COMPLETED SUICIDE	2000Q1	0	0
COMPLETED SUICIDE	2000Q2	3	1
COMPLETED SUICIDE	2000Q3	1	0
COMPLETED SUICIDE	2000Q4	1	0
COMPLETED SUICIDE	2001Q1	1	1
COMPLETED SUICIDE	2001Q2	1	0
COMPLETED SUICIDE	2001Q3	5	0
COMPLETED SUICIDE	2001Q4	7	0
COMPLETED SUICIDE	2002Q1	2	0
COMPLETED SUICIDE	2002Q2	3	2
COMPLETED SUICIDE	2002Q3	7	1
COMPLETED SUICIDE	2002Q4	8	3
COMPLETED SUICIDE	2003Q1	12	6
COMPLETED SUICIDE	2003Q2	16	11

Petitioners' Summary of Neurontin A.E.R.S. Events

Table 2. Suicide Attempts

Preferred Term	Date	Total Count	Pfizer Count
SUICIDE ATTEMPT	1998Q1	0	0
SUICIDE ATTEMPT	1998Q2	0	0
SUICIDE ATTEMPT	1998Q3	2	0
SUICIDE ATTEMPT	1998Q4	0	0
SUICIDE ATTEMPT	1999Q1	2	1
SUICIDE ATTEMPT	1999Q2	2	0
SUICIDE ATTEMPT	1999Q3	7	0
SUICIDE ATTEMPT	1999Q4	2	1
SUICIDE ATTEMPT	2000Q1	4	3
SUICIDE ATTEMPT	2000Q2	2	0
SUICIDE ATTEMPT	2000Q3	7	2
SUICIDE ATTEMPT	2000Q4	6	2
SUICIDE ATTEMPT	2001Q1	7	3
SUICIDE ATTEMPT	2001Q2	7	4
SUICIDE ATTEMPT	2001Q3	2	1
SUICIDE ATTEMPT	2001Q4	4	0
SUICIDE ATTEMPT	2002Q1	6	2
SUICIDE ATTEMPT	2002Q2	5	2
SUICIDE ATTEMPT	2002Q3	4	1
SUICIDE ATTEMPT	2002Q4	6	0
SUICIDE ATTEMPT	2003Q1	6	3
SUICIDE ATTEMPT	2003Q2	8	1

Petitioners' Summary of Neurontin A.E.R.S. Events

Table 3. Suicidal Ideation

Preferred Term	Date	Total Count	Pfizer Count
SUICIDAL IDEATION	1998Q1	0	0
SUICIDAL IDEATION	1998Q2	0	0
SUICIDAL IDEATION	1998Q3	0	0
SUICIDAL IDEATION	1998Q4	2	1
SUICIDAL IDEATION	1999Q1	4	4
SUICIDAL IDEATION	1999Q2	3	1
SUICIDAL IDEATION	1999Q3	2	0
SUICIDAL IDEATION	1999Q4	4	1
SUICIDAL IDEATION	2000Q1	4	4
SUICIDAL IDEATION	2000Q2	3	1
SUICIDAL IDEATION	2000Q3	3	0
SUICIDAL IDEATION	2000Q4	4	0
SUICIDAL IDEATION	2001Q1	3	1
SUICIDAL IDEATION	2001Q2	3	2
SUICIDAL IDEATION	2001Q3	4	1
SUICIDAL IDEATION	2001Q4	5	1
SUICIDAL IDEATION	2002Q1	7	5
SUICIDAL IDEATION	2002Q2	8	2
SUICIDAL IDEATION	2002Q3	6	0
SUICIDAL IDEATION	2002Q4	13	3
SUICIDAL IDEATION	2003Q1	8	3
SUICIDAL IDEATION	2003Q2	8	0

C. The Petitioners' Review of the Completed Suicide Reports and Other Related Events Submitted to FDA's A.E.R.S. Database Confirms the Necessity and Urgency of the Proposed Labeling Additions.

In the first six months of 2003, Pfizer reported 17 new events of completed suicide. These events represent approximately 6% of all the expedited adverse events reported by Pfizer for Neurontin in this same period. These 17 new events of completed suicide also represent a sharp and startling increase in the number of reported postmarketing suicides. Obviously, any event representing these contributions to the total numbers of serious and fatal events must be specifically listed in all product labeling. Fatality-associated events also require highlighted positioning in all Neurontin labeling and promotional pieces.

The Petitioners have appended summaries of the completed suicide reports provided to A.E.R.S. in Attachment 2. These reports have been designated by Pfizer as expedited reports and are derived from healthcare professionals, consumers, and the scientific literature. When provided, the indications note the unlabeled uses of peripheral neuropathy, bipolar disorders and pain. Neurontin is considered the primary suspect agent in all but one of these suicide fatality reports. Neurontin is listed as sole therapy in approximately twenty-five percent of these reports.

Suicide attempts and suicidal ideations have been steadily noted in postmarketing reports submitted between 1998 and 2003. To date, Pfizer has reported a total of 26 reports of suicide attempts and 30 reports of suicidal ideations.

Given the frequency, magnitude and critical nature of these reports, it is readily apparent that postmarketing reports of completed suicide, as well as suicide attempts and ideations must be immediately added to the Neurontin insert. This information must be highlighted in all three labeling sections related to drug product safety. Given the critical safety issues evidenced in completed suicide reports, a Black Box Warning is also required to increase the prescribers' focus on these potentially fatal events.

The new labeling information must also be disseminated as expeditiously as possible to healthcare providers. The Petitioners believe all U.S. prescribers and healthcare associated professionals must be provided with immediate Dear Doctor and Dear Healthcare Professional letters outlining the escalating number of fatal suicide events. Additional methods and venues of communication with prescribers and patients may also be warranted because of Neurontin's significant commercialization for non-labeled indications by a wide variety of prescribers.

III. Environmental Impact Statement

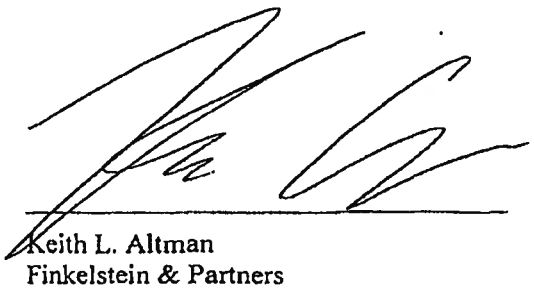
The Petitioners believe the actions requested in this Petition provide no significant environmental impact. The requested actions will not introduce any substance into the environment and is categorically excluded pursuant to 21 CFR 25.30.

IV. Economic Impact Statement

This information is only to be submitted when requested by the Commissioner following a review of this petition.

V. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies and that it includes representative data and information known to the petitioners which are unfavorable to the petition.



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May 17, 2004

Attachment 1
Current Neurontin Labeling

Neurontin® (gabapentin) Capsules
Neurontin® (gabapentin) Tablets
Neurontin® (gabapentin) Oral Solution

DESCRIPTION

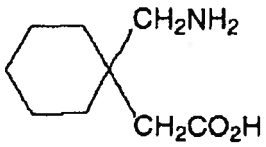
Neurontin® (gabapentin) Capsules, Neurontin® (gabapentin) Tablets, and Neurontin® (gabapentin) Oral Solution are supplied as imprinted hard shell capsules containing 100 mg, 300 mg, and 400 mg of gabapentin, elliptical film-coated tablets containing 600 mg and 800 mg of gabapentin or an oral solution containing 250 mg/5 mL of gabapentin.

The inactive ingredients for the capsules are lactose, cornstarch, and talc. The 100 mg capsule shell contains gelatin and titanium dioxide. The 300 mg capsule shell contains gelatin, titanium dioxide, and yellow iron oxide. The 400 mg capsule shell contains gelatin, red iron oxide, titanium dioxide, and yellow iron oxide. The imprinting ink contains FD&C Blue No. 2 and titanium dioxide.

The inactive ingredients for the tablets are poloxamer 407, copolyvidonum, cornstarch, magnesium stearate, hydroxypropyl cellulose, talc, candelilla wax and purified water.

The inactive ingredients for the oral solution are glycerin, xylitol, purified water and artificial cool strawberry anise flavor.

Gabapentin is described as 1-(aminomethyl)cyclohexaneacetic acid with a molecular formula of $C_9H_{17}NO_2$ and a molecular weight of 171.24. The structural formula of gabapentin is:



Gabapentin is a white to off-white crystalline solid with a pK_{a1} of 3.7 and a pK_{a2} of 10.7. It is freely soluble in water and both basic and acidic aqueous solutions. The log of the partition coefficient (n-octanol/0.05M phosphate buffer) at pH 7.4 is –1.25.

CLINICAL PHARMACOLOGY

Mechanism of Action

The mechanism by which gabapentin exerts its analgesic action is unknown, but in animal models of analgesia, gabapentin prevents allodynia (pain-related behavior in response to a normally innocuous stimulus) and hyperalgesia (exaggerated response to painful stimuli). In

particular, gabapentin prevents pain-related responses in several models of neuropathic pain in rats or mice (e.g. spinal nerve ligation models, streptozocin-induced diabetes model, spinal cord injury model, acute herpes zoster infection model). Gabapentin also decreases pain-related responses after peripheral inflammation (carrageenan footpad test, late phase of formalin test). Gabapentin did not alter immediate pain-related behaviors (rat tail flick test, formalin footpad acute phase, acetic acid abdominal constriction test, footpad heat irradiation test). The relevance of these models to human pain is not known.

The mechanism by which gabapentin exerts its anticonvulsant action is unknown, but in animal test systems designed to detect anticonvulsant activity, gabapentin prevents seizures as do other marketed anticonvulsants. Gabapentin exhibits antiseizure activity in mice and rats in both the maximal electroshock and pentylenetetrazole seizure models and other preclinical models (e.g., strains with genetic epilepsy, etc.). The relevance of these models to human epilepsy is not known.

Gabapentin is structurally related to the neurotransmitter GABA (gamma-aminobutyric acid) but it does not modify $GABA_A$ or $GABA_B$ radioligand binding, it is not converted metabolically into GABA or a GABA agonist, and it is not an inhibitor of GABA uptake or degradation. Gabapentin was tested in radioligand binding assays at concentrations up to 100 μM and did not exhibit affinity for a number of other common receptor sites, including benzodiazepine, glutamate, N-methyl-D-aspartate (NMDA), quisqualate, kainate, strychnine-insensitive or strychnine-sensitive glycine, alpha 1, alpha 2, or beta adrenergic, adenosine A1 or A2, cholinergic muscarinic or nicotinic, dopamine D1 or D2, histamine H1, serotonin S1 or S2, opiate mu, delta or kappa, cannabinoid 1, voltage-sensitive calcium channel sites labeled with nitrendipine or diltiazem, or at voltage-sensitive sodium channel sites labeled with batrachotoxinin A 20-alpha-benzoate. Furthermore, gabapentin did not alter the cellular uptake of dopamine, noradrenaline, or serotonin.

In vitro studies with radiolabeled gabapentin have revealed a gabapentin binding site in areas of rat brain including neocortex and hippocampus. A high-affinity binding protein in animal brain tissue has been identified as an auxiliary subunit of voltage-activated calcium channels. However, functional correlates of gabapentin binding, if any, remain to be elucidated.

Pharmacokinetics and Drug Metabolism

All pharmacological actions following gabapentin administration are due to the activity of the parent compound; gabapentin is not appreciably metabolized in humans.

Oral Bioavailability: Gabapentin bioavailability is not dose proportional; i.e., as dose is increased, bioavailability decreases. Bioavailability of gabapentin is approximately 60%, 47%, 34%, 33%, and 27% following 900, 1200, 2400, 3600, and 4800 mg/day given in 3 divided doses, respectively. Food has only a slight effect on the rate and extent of absorption of gabapentin (14% increase in AUC and C_{max}).

Distribution: Less than 3% of gabapentin circulates bound to plasma protein. The apparent volume of distribution of gabapentin after 150 mg intravenous administration is 58±6 L (Mean ±SD). In patients with epilepsy, steady-state predose (C_{min}) concentrations of gabapentin in cerebrospinal fluid were approximately 20% of the corresponding plasma concentrations.

Elimination: Gabapentin is eliminated from the systemic circulation by renal excretion as unchanged drug. Gabapentin is not appreciably metabolized in humans.

Gabapentin elimination half-life is 5 to 7 hours and is unaltered by dose or following multiple dosing. Gabapentin elimination rate constant, plasma clearance, and renal clearance are directly proportional to creatinine clearance (see Special Populations: Patients With Renal Insufficiency, below). In elderly patients, and in patients with impaired renal function, gabapentin plasma clearance is reduced. Gabapentin can be removed from plasma by hemodialysis.

Dosage adjustment in patients with compromised renal function or undergoing hemodialysis is recommended (see DOSAGE AND ADMINISTRATION, Table 5).

Special Populations: *Adult Patients With Renal Insufficiency:* Subjects (N=60) with renal insufficiency (mean creatinine clearance ranging from 13-114 mL/min) were administered single 400 mg oral doses of gabapentin. The mean gabapentin half-life ranged from about 6.5 hours (patients with creatinine clearance >60 mL/min) to 52 hours (creatinine clearance <30 mL/min) and gabapentin renal clearance from about 90 mL/min (>60 mL/min group) to about 10 mL/min (<30 mL/min). Mean plasma clearance (CL/F) decreased from approximately 190 mL/min to 20 mL/min.

Dosage adjustment in adult patients with compromised renal function is necessary (see DOSAGE AND ADMINISTRATION). Pediatric patients with renal insufficiency have not been studied.

Hemodialysis: In a study in anuric adult subjects (N=11), the apparent elimination half-life of gabapentin on nondialysis days was about 132 hours; during dialysis the apparent half-life of gabapentin was reduced to 3.8 hours. Hemodialysis thus has a significant effect on gabapentin elimination in anuric subjects.

Dosage adjustment in patients undergoing hemodialysis is necessary (see DOSAGE AND ADMINISTRATION).

Hepatic Disease: Because gabapentin is not metabolized, no study was performed in patients with hepatic impairment.

Age: The effect of age was studied in subjects 20-80 years of age. Apparent oral clearance (CL/F) of gabapentin decreased as age increased, from about 225 mL/min in those under 30 years of age to about 125 mL/min in those over 70 years of age. Renal clearance (CLr) and CLr adjusted for body surface area also declined with age; however, the decline in the renal clearance of gabapentin with age can largely be explained by the decline in renal function. Reduction of gabapentin dose may be required in patients who have age related compromised renal function. (See PRECAUTIONS, Geriatric Use, and DOSAGE AND ADMINISTRATION.)

Pediatric: Gabapentin pharmacokinetics were determined in 48 pediatric subjects between the ages of 1 month and 12 years following a dose of approximately 10 mg/kg. Peak plasma concentrations were similar across the entire age group and occurred 2 to 3 hours postdose. In general, pediatric subjects between 1 month and <5 years of age achieved approximately 30% lower exposure (AUC) than that observed in those 5 years of age and older. Accordingly, oral clearance normalized per body weight was higher in the younger children. Apparent oral clearance of gabapentin was directly proportional to creatinine clearance. Gabapentin elimination half-life averaged 4.7 hours and was similar across the age groups studied.

A population pharmacokinetic analysis was performed in 253 pediatric subjects between 1 month and 13 years of age. Patients received 10 to 65 mg/kg/day given TID. Apparent oral clearance (CL/F) was directly proportional to creatinine clearance and this relationship was similar following a single dose and at steady state. Higher oral clearance values were observed in children <5 years of age compared to those observed in children 5 years of age and older, when normalized per body weight. The clearance was highly variable in infants <1 year of age. The normalized CL/F values observed in pediatric patients 5 years of age and older were consistent with values observed in adults after a single dose. The oral volume of distribution normalized per body weight was constant across the age range.

These pharmacokinetic data indicate that the effective daily dose in pediatric patients with epilepsy ages 3 and 4 years should be 40 mg/kg/day to achieve average plasma concentrations similar to those achieved in patients 5 years of age and older receiving gabapentin at 30 mg/kg/day (see DOSAGE AND ADMINISTRATION).

Gender: Although no formal study has been conducted to compare the pharmacokinetics of gabapentin in men and women, it appears that the pharmacokinetic parameters for males and females are similar and there are no significant gender differences.

Race: Pharmacokinetic differences due to race have not been studied. Because gabapentin is primarily renally excreted and there are no important racial differences in creatinine clearance, pharmacokinetic differences due to race are not expected.

Clinical Studies

Postherpetic Neuralgia

Neurontin® was evaluated for the management of postherpetic neuralgia (PHN) in 2 randomized, double-blind, placebo-controlled, multicenter studies; N=563 patients in the intent-to-treat (ITT) population (Table 1). Patients were enrolled if they continued to have pain for more than 3 months after healing of the herpes zoster skin rash.

TABLE 1. Controlled PHN Studies: Duration, Dosages, and Number of Patients

Study	Study Duration	Gabapentin (mg/day)[a] Target Dose	Patients Receiving Gabapentin	Patients Receiving Placebo
1	8 weeks	3600	113	116
2	7 weeks	1800, 2400	223	111
		Total	336	227

[a] Given in 3 divided doses (TID)

Each study included a 1-week baseline during which patients were screened for eligibility and a 7- or 8-week double-blind phase (3 or 4 weeks of titration and 4 weeks of fixed dose). Patients initiated treatment with titration to a maximum of 900 mg/day gabapentin over 3 days. Dosages were then to be titrated in 600 to 1200 mg/day increments at 3- to 7-day intervals to target dose over 3 to 4 weeks. In Study 1, patients were continued on lower doses if not able to achieve the target dose. During baseline and treatment, patients recorded their pain in a daily diary using an

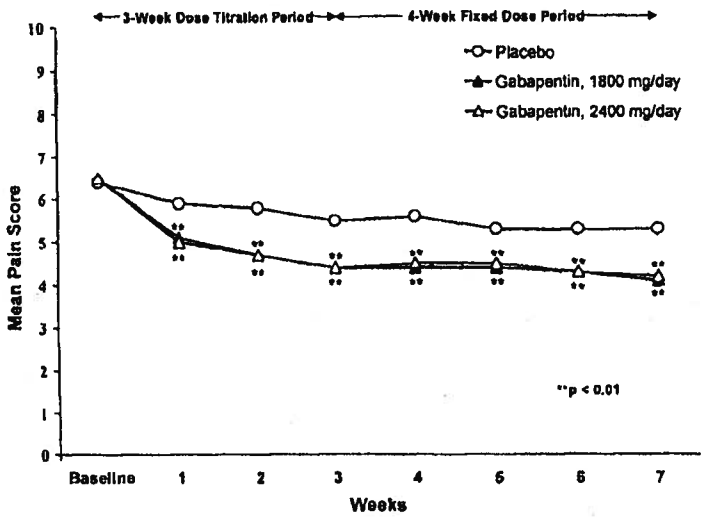


Figure 2. Weekly Mean Pain Scores (Observed Cases in ITT Population): Study 2

The proportion of responders (those patients reporting at least 50% improvement in endpoint pain score compared with baseline) was calculated for each study (Figure 3).

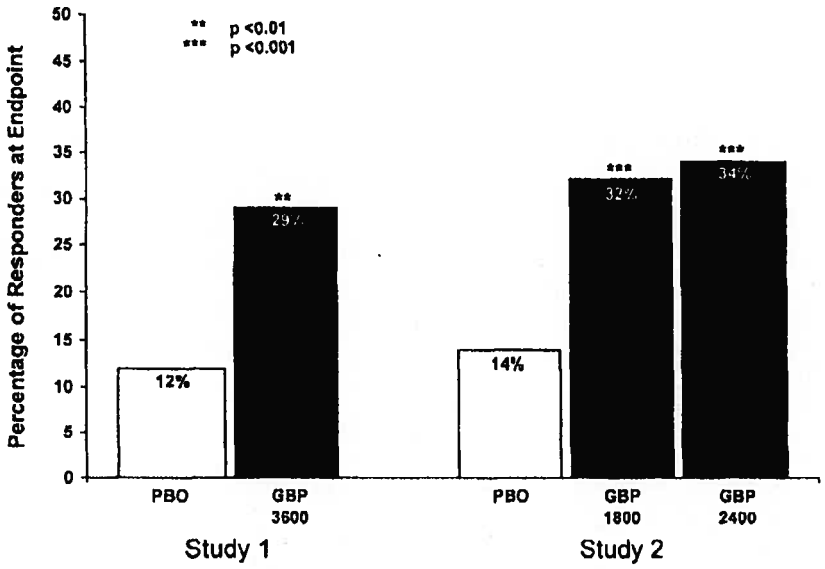


Figure 3. Proportion of Responders (patients with ≥50% reduction in pain score) at Endpoint: Controlled PHN Studies

Epilepsy

The effectiveness of Neurontin® as adjunctive therapy (added to other antiepileptic drugs) was established in multicenter placebo-controlled, double-blind, parallel-group clinical trials in adult and pediatric patients (3 years and older) with refractory partial seizures.

Evidence of effectiveness was obtained in three trials conducted in 705 patients (age 12 years and above) and one trial conducted in 247 pediatric patients (3 to 12 years of age). The patients enrolled had a history of at least 4 partial seizures per month in spite of receiving one or more antiepileptic drugs at therapeutic levels and were observed on their established antiepileptic drug regimen during a 12-week baseline period (6 weeks in the study of pediatric patients). In patients continuing to have at least 2 (or 4 in some studies) seizures per month, Neurontin® or placebo was then added on to the existing therapy during a 12-week treatment period. Effectiveness was assessed primarily on the basis of the percent of patients with a 50% or greater reduction in seizure frequency from baseline to treatment (the "responder rate") and a derived measure called response ratio, a measure of change defined as (T - B)/(T + B), where B is the patient's baseline seizure frequency and T is the patient's seizure frequency during treatment. Response ratio is distributed within the range -1 to +1. A zero value indicates no change while complete elimination of seizures would give a value of -1; increased seizure rates would give positive values. A response ratio of -0.33 corresponds to a 50% reduction in seizure frequency. The

results given below are for all partial seizures in the intent-to-treat (all patients who received any doses of treatment) population in each study, unless otherwise indicated.

One study compared Neurontin® 1200 mg/day divided TID with placebo. Responder rate was 23% (14/61) in the Neurontin® group and 9% (6/66) in the placebo group; the difference between groups was statistically significant. Response ratio was also better in the Neurontin® group (-0.199) than in the placebo group (-0.044), a difference that also achieved statistical significance.

A second study compared primarily 1200 mg/day divided TID Neurontin® (N=101) with placebo (N=98). Additional smaller Neurontin® dosage groups (600 mg/day, N=53; 1800 mg/day, N=54) were also studied for information regarding dose response. Responder rate was higher in the Neurontin® 1200 mg/day group (16%) than in the placebo group (8%), but the difference was not statistically significant. The responder rate at 600 mg (17%) was also not significantly higher than in the placebo, but the responder rate in the 1800 mg group (26%) was statistically significantly superior to the placebo rate. Response ratio was better in the Neurontin® 1200 mg/day group (-0.103) than in the placebo group (-0.022); but this difference was also not statistically significant ($p = 0.224$). A better response was seen in the Neurontin® 600 mg/day group (-0.105) and 1800 mg/day group (-0.222) than in the 1200 mg/day group, with the 1800 mg/day group achieving statistical significance compared to the placebo group.

A third study compared Neurontin® 900 mg/day divided TID (N=111) and placebo (N=109). An additional Neurontin® 1200 mg/day dosage group (N=52) provided dose-response data. A statistically significant difference in responder rate was seen in the Neurontin® 900 mg/day group (22%) compared to that in the placebo group (10%). Response ratio was also statistically significantly superior in the Neurontin® 900 mg/day group (-0.119) compared to that in the placebo group (-0.027), as was response ratio in 1200 mg/day Neurontin® (-0.184) compared to placebo.

Analyses were also performed in each study to examine the effect of Neurontin® on preventing secondarily generalized tonic-clonic seizures. Patients who experienced a secondarily generalized tonic-clonic seizure in either the baseline or in the treatment period in all three placebo-controlled studies were included in these analyses. There were several response ratio comparisons that showed a statistically significant advantage for Neurontin® compared to placebo and favorable trends for almost all comparisons.

Analysis of responder rate using combined data from all three studies and all doses (N=162, Neurontin®; N=89, placebo) also showed a significant advantage for Neurontin® over placebo in reducing the frequency of secondarily generalized tonic-clonic seizures.

In two of the three controlled studies, more than one dose of Neurontin® was used. Within each study the results did not show a consistently increased response to dose. However, looking across studies, a trend toward increasing efficacy with increasing dose is evident (see Figure 4).

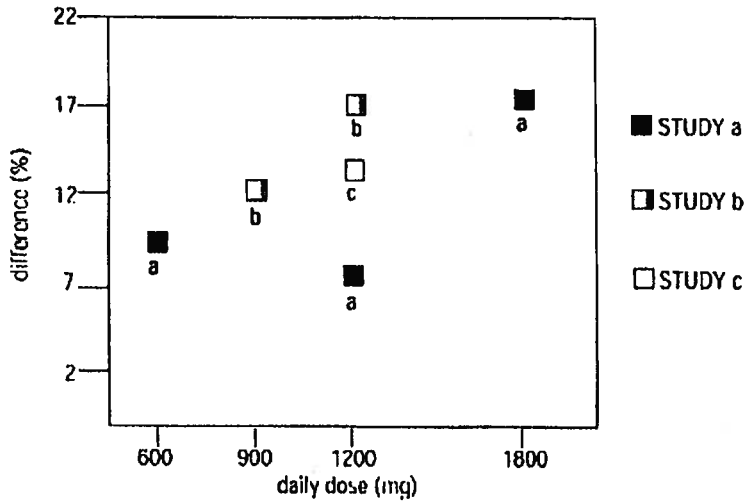


Figure 4. Responder Rate in Patients Receiving Neurontin® Expressed as a Difference from Placebo by Dose and Study: Adjunctive Therapy Studies in Patients ≥12 Years of Age with Partial Seizures

In the figure, treatment effect magnitude, measured on the Y axis in terms of the difference in the proportion of gabapentin and placebo assigned patients attaining a 50% or greater reduction in seizure frequency from baseline, is plotted against the daily dose of gabapentin administered (X axis).

Although no formal analysis by gender has been performed, estimates of response (Response Ratio) derived from clinical trials (398 men, 307 women) indicate no important gender differences exist. There was no consistent pattern indicating that age had any effect on the response to Neurontin®. There were insufficient numbers of patients of races other than Caucasian to permit a comparison of efficacy among racial groups.

A fourth study in pediatric patients age 3 to 12 years compared 25 – 35 mg/kg/day Neurontin® (N=118) with placebo (N=127). For all partial seizures in the intent-to-treat population, the response ratio was statistically significantly better for the Neurontin® group (-0.146) than for the placebo group (-0.079). For the same population, the responder rate for Neurontin® (21%) was not significantly different from placebo (18%).

A study in pediatric patients age 1 month to 3 years compared 40 mg/kg/day Neurontin® (N=38) with placebo (N=38) in patients who were receiving at least one marketed antiepileptic drug and had at least one partial seizure during the screening period (within 2 weeks prior to baseline). Patients had up to 48 hours of baseline and up to 72 hours of double-blind video EEG monitoring to record and count the occurrence of seizures. There were no statistically significant differences between treatments in either the response ratio or responder rate.

INDICATIONS AND USAGE

Postherpetic Neuralgia

Neurontin® (gabapentin) is indicated for the management of postherpetic neuralgia in adults.

Epilepsy

Neurontin® (gabapentin) is indicated as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in patients over 12 years of age with epilepsy. Neurontin is also indicated as adjunctive therapy in the treatment of partial seizures in pediatric patients age 3 – 12 years.

CONTRAINDICATIONS

Neurontin® is contraindicated in patients who have demonstrated hypersensitivity to the drug or its ingredients.

WARNINGS

Neuropsychiatric Adverse Events—Pediatric Patients 3-12 years of age

Gabapentin use in pediatric patients with epilepsy 3–12 years of age is associated with the occurrence of central nervous system related adverse events. The most significant of these can be classified into the following categories: 1) emotional lability (primarily behavioral problems), 2) hostility, including aggressive behaviors, 3) thought disorder, including concentration problems and change in school performance, and 4) hyperkinesia (primarily restlessness and hyperactivity). Among the gabapentin-treated patients, most of the events were mild to moderate in intensity.

In controlled trials in pediatric patients 3–12 years of age the incidence of these adverse events was: emotional lability 6% (gabapentin-treated patients) vs 1.3% (placebo-treated patients); hostility 5.2% vs 1.3%; hyperkinesia 4.7% vs 2.9%; and thought disorder 1.7% vs 0%. One of these events, a report of hostility, was considered serious. Discontinuation of gabapentin treatment occurred in 1.3% of patients reporting emotional lability and hyperkinesia and 0.9% of gabapentin-treated patients reporting hostility and thought disorder. One placebo-treated patient (0.4%) withdrew due to emotional lability.

Withdrawal Precipitated Seizure, Status Epilepticus

Antiepileptic drugs should not be abruptly discontinued because of the possibility of increasing seizure frequency.

In the placebo-controlled studies in patients >12 years of age, the incidence of status epilepticus in patients receiving Neurontin® was 0.6% (3 of 543) versus 0.5% in patients receiving placebo (2 of 378). Among the 2074 patients >12 years of age treated with Neurontin® across all studies (controlled and uncontrolled) 31 (1.5%) had status epilepticus. Of these, 14 patients had no prior history of status epilepticus either before treatment or while on other medications. Because adequate historical data are not available, it is impossible to say whether or not treatment with

Neurontin® is associated with a higher or lower rate of status epilepticus than would be expected to occur in a similar population not treated with Neurontin®.

Tumorigenic Potential

In standard preclinical *in vivo* lifetime carcinogenicity studies, an unexpectedly high incidence of pancreatic acinar adenocarcinomas was identified in male, but not female, rats. (See PRECAUTIONS: Carcinogenesis, Mutagenesis, Impairment of Fertility.) The clinical significance of this finding is unknown. Clinical experience during gabapentin's premarketing development provides no direct means to assess its potential for inducing tumors in humans.

In clinical studies in adjunctive therapy in epilepsy comprising 2085 patient-years of exposure in patients >12 years of age, new tumors were reported in 10 patients (2 breast, 3 brain, 2 lung, 1 adrenal, 1 non-Hodgkin's lymphoma, 1 endometrial carcinoma *in situ*), and preexisting tumors worsened in 11 patients (9 brain, 1 breast, 1 prostate) during or up to 2 years following discontinuation of Neurontin®. Without knowledge of the background incidence and recurrence in a similar population not treated with Neurontin®, it is impossible to know whether the incidence seen in this cohort is or is not affected by treatment.

Sudden and Unexplained Death in Patients With Epilepsy

During the course of premarketing development of Neurontin® 8 sudden and unexplained deaths were recorded among a cohort of 2203 patients treated (2103 patient-years of exposure).

Some of these could represent seizure-related deaths in which the seizure was not observed, e.g., at night. This represents an incidence of 0.0038 deaths per patient-year. Although this rate exceeds that expected in a healthy population matched for age and sex, it is within the range of estimates for the incidence of sudden unexplained deaths in patients with epilepsy not receiving Neurontin® (ranging from 0.0005 for the general population of epileptics to 0.003 for a clinical trial population similar to that in the Neurontin® program, to 0.005 for patients with refractory epilepsy). Consequently, whether these figures are reassuring or raise further concern depends on comparability of the populations reported upon to the Neurontin® cohort and the accuracy of the estimates provided.

PRECAUTIONS

Information for Patients

Patients should be instructed to take Neurontin® only as prescribed.

Patients should be advised that Neurontin® may cause dizziness, somnolence and other symptoms and signs of CNS depression. Accordingly, they should be advised neither to drive a car nor to operate other complex machinery until they have gained sufficient experience on Neurontin® to gauge whether or not it affects their mental and/or motor performance adversely.

Patients who require concomitant treatment with morphine may experience increases in gabapentin concentrations. Patients should be carefully observed for signs of CNS depression, such as somnolence, and the dose of Neurontin® or morphine should be reduced appropriately (see Drug Interactions).

Laboratory Tests

Clinical trials data do not indicate that routine monitoring of clinical laboratory parameters is necessary for the safe use of Neurontin®. The value of monitoring gabapentin blood

concentrations has not been established. Neurontin® may be used in combination with other antiepileptic drugs without concern for alteration of the blood concentrations of gabapentin or of other antiepileptic drugs.

Drug Interactions

In vitro studies were conducted to investigate the potential of gabapentin to inhibit the major cytochrome P450 enzymes (CYP1A2, CYP2A6, CYP2C9, CYP2C19, CYP2D6, CYP2E1, and CYP3A4) that mediate drug and xenobiotic metabolism using isoform selective marker substrates and human liver microsomal preparations. Only at the highest concentration tested (171 µg/mL; 1 mM) was a slight degree of inhibition (14%-30%) of isoform CYP2A6 observed. No inhibition of any of the other isoforms tested was observed at gabapentin concentrations up to 171 µg/mL (approximately 15 times the C_{max} at 3600 mg/day).

Gabapentin is not appreciably metabolized nor does it interfere with the metabolism of commonly coadministered antiepileptic drugs.

The drug interaction data described in this section were obtained from studies involving healthy adults and adult patients with epilepsy.

Phenytoin: In a single (400 mg) and multiple dose (400 mg TID) study of Neurontin® in epileptic patients (N=8) maintained on phenytoin monotherapy for at least 2 months, gabapentin had no effect on the steady-state trough plasma concentrations of phenytoin and phenytoin had no effect on gabapentin pharmacokinetics.

Carbamazepine: Steady-state trough plasma carbamazepine and carbamazepine 10, 11 epoxide concentrations were not affected by concomitant gabapentin (400 mg TID; N=12) administration. Likewise, gabapentin pharmacokinetics were unaltered by carbamazepine administration.

Valproic Acid: The mean steady-state trough serum valproic acid concentrations prior to and during concomitant gabapentin administration (400 mg TID; N=17) were not different and neither were gabapentin pharmacokinetic parameters affected by valproic acid.

Phenobarbital: Estimates of steady-state pharmacokinetic parameters for phenobarbital or gabapentin (300 mg TID; N=12) are identical whether the drugs are administered alone or together.

Naproxen: Coadministration (N=18) of naproxen sodium capsules (250 mg) with Neurontin® (125 mg) appears to increase the amount of gabapentin absorbed by 12% to 15%. Gabapentin had no effect on naproxen pharmacokinetic parameters. These doses are lower than the therapeutic doses for both drugs. The magnitude of interaction within the recommended dose ranges of either drug is not known.

Hydrocodone: Coadministration of Neurontin® (125 to 500 mg; N=48) decreases hydrocodone (10 mg; N=50) C_{max} and AUC values in a dose-dependent manner relative to administration of hydrocodone alone; C_{max} and AUC values are 3% to 4% lower, respectively, after administration of 125 mg Neurontin® and 21% to 22% lower, respectively, after administration of 500 mg Neurontin®. The mechanism for this interaction is unknown. Hydrocodone increases gabapentin AUC values by 14%. The magnitude of interaction at other doses is not known.

Morphine: A literature article reported that when a 60-mg controlled-release morphine capsule was administered 2 hours prior to a 600-mg Neurontin® capsule (N=12), mean gabapentin AUC

increased by 44% compared to gabapentin administered without morphine (see PRECAUTIONS). Morphine pharmacokinetic parameter values were not affected by administration of Neurontin® 2 hours after morphine. The magnitude of interaction at other doses is not known.

Cimetidine: In the presence of cimetidine at 300 mg QID (N=12) the mean apparent oral clearance of gabapentin fell by 14% and creatinine clearance fell by 10%. Thus cimetidine appeared to alter the renal excretion of both gabapentin and creatinine, an endogenous marker of renal function. This small decrease in excretion of gabapentin by cimetidine is not expected to be of clinical importance. The effect of gabapentin on cimetidine was not evaluated.

Oral Contraceptive: Based on AUC and half-life, multiple-dose pharmacokinetic profiles of norethindrone and ethinyl estradiol following administration of tablets containing 2.5 mg of norethindrone acetate and 50 mcg of ethinyl estradiol were similar with and without coadministration of gabapentin (400 mg TID; N=13). The Cmax of norethindrone was 13% higher when it was coadministered with gabapentin; this interaction is not expected to be of clinical importance.

Antacid (Maalox®): Maalox reduced the bioavailability of gabapentin (N=16) by about 20%. This decrease in bioavailability was about 5% when gabapentin was administered 2 hours after Maalox. It is recommended that gabapentin be taken at least 2 hours following Maalox administration.

Effect of Probenecid: Probenecid is a blocker of renal tubular secretion. Gabapentin pharmacokinetic parameters without and with probenecid were comparable. This indicates that gabapentin does not undergo renal tubular secretion by the pathway that is blocked by probenecid.

Drug/Laboratory Tests Interactions

Because false positive readings were reported with the Ames N-Multistix SG® dipstick test for urinary protein when gabapentin was added to other antiepileptic drugs, the more specific sulfosalicylic acid precipitation procedure is recommended to determine the presence of urine protein.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Gabapentin was given in the diet to mice at 200, 600, and 2000 mg/kg/day and to rats at 250, 1000, and 2000 mg/kg/day for 2 years. A statistically significant increase in the incidence of pancreatic acinar cell adenomas and carcinomas was found in male rats receiving the high dose; the no-effect dose for the occurrence of carcinomas was 1000 mg/kg/day. Peak plasma concentrations of gabapentin in rats receiving the high dose of 2000 mg/kg were 10 times higher than plasma concentrations in humans receiving 3600 mg per day, and in rats receiving 1000 mg/kg/day peak plasma concentrations were 6.5 times higher than in humans receiving 3600 mg/day. The pancreatic acinar cell carcinomas did not affect survival, did not metastasize and were not locally invasive. The relevance of this finding to carcinogenic risk in humans is unclear.

Studies designed to investigate the mechanism of gabapentin-induced pancreatic carcinogenesis in rats indicate that gabapentin stimulates DNA synthesis in rat pancreatic acinar cells *in vitro* and, thus, may be acting as a tumor promoter by enhancing mitogenic activity. It is not known

whether gabapentin has the ability to increase cell proliferation in other cell types or in other species, including humans.

Gabapentin did not demonstrate mutagenic or genotoxic potential in three *in vitro* and four *in vivo* assays. It was negative in the Ames test and the *in vitro* HGPRT forward mutation assay in Chinese hamster lung cells; it did not produce significant increases in chromosomal aberrations in the *in vitro* Chinese hamster lung cell assay; it was negative in the *in vivo* chromosomal aberration assay and in the *in vivo* micronucleus test in Chinese hamster bone marrow; it was negative in the *in vivo* mouse micronucleus assay; and it did not induce unscheduled DNA synthesis in hepatocytes from rats given gabapentin.

No adverse effects on fertility or reproduction were observed in rats at doses up to 2000 mg/kg (approximately 5 times the maximum recommended human dose on a mg/m^2 basis).

Pregnancy

Pregnancy Category C: Gabapentin has been shown to be fetotoxic in rodents, causing delayed ossification of several bones in the skull, vertebrae, forelimbs, and hindlimbs. These effects occurred when pregnant mice received oral doses of 1000 or 3000 mg/kg/day during the period of organogenesis, or approximately 1 to 4 times the maximum dose of 3600 mg/day given to epileptic patients on a mg/m^2 basis. The no-effect level was 500 mg/kg/day or approximately ½ of the human dose on a mg/m^2 basis.

When rats were dosed prior to and during mating, and throughout gestation, pups from all dose groups (500, 1000 and 2000 mg/kg/day) were affected. These doses are equivalent to less than approximately 1 to 5 times the maximum human dose on a mg/m^2 basis. There was an increased incidence of hydroureter and/or hydronephrosis in rats in a study of fertility and general reproductive performance at 2000 mg/kg/day with no effect at 1000 mg/kg/day, in a teratology study at 1500 mg/kg/day with no effect at 300 mg/kg/day, and in a perinatal and postnatal study at all doses studied (500, 1000 and 2000 mg/kg/day). The doses at which the effects occurred are approximately 1 to 5 times the maximum human dose of 3600 mg/day on a mg/m^2 basis; the no-effect doses were approximately 3 times (Fertility and General Reproductive Performance study) and approximately equal to (Teratogenicity study) the maximum human dose on a mg/m^2 basis. Other than hydroureter and hydronephrosis, the etiologies of which are unclear, the incidence of malformations was not increased compared to controls in offspring of mice, rats, or rabbits given doses up to 50 times (mice), 30 times (rats), and 25 times (rabbits) the human daily dose on a mg/kg basis, or 4 times (mice), 5 times (rats), or 8 times (rabbits) the human daily dose on a mg/m^2 basis.

In a teratology study in rabbits, an increased incidence of postimplantation fetal loss occurred in dams exposed to 60, 300, and 1500 mg/kg/day, or less than approximately ¼ to 8 times the maximum human dose on a mg/m^2 basis. There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Use in Nursing Mothers

Gabapentin is secreted into human milk following oral administration. A nursed infant could be exposed to a maximum dose of approximately 1 mg/kg/day of gabapentin. Because the effect on the nursing infant is unknown, Neurontin® should be used in women who are nursing only if the benefits clearly outweigh the risks.

Pediatric Use

Safety and effectiveness of Neurontin® (gabapentin) in the management of postherpetic neuralgia in pediatric patients have not been established.

Effectiveness as adjunctive therapy in the treatment of partial seizures in pediatric patients below the age of 3 years has not been established (see CLINICAL PHARMACOLOGY, Clinical Studies).

Geriatric Use

The total number of patients treated with Neurontin® in controlled clinical trials in patients with postherpetic neuralgia was 336, of which 102 (30%) were 65 to 74 years of age, and 168 (50%) were 75 years of age and older. There was a larger treatment effect in patients 75 years of age and older compared with younger patients who received the same dosage. Since gabapentin is almost exclusively eliminated by renal excretion, the larger treatment effect observed in patients ≥75 years may be a consequence of increased gabapentin exposure for a given dose that results from an age-related decrease in renal function. However, other factors cannot be excluded. The types and incidence of adverse events were similar across age groups except for peripheral edema and ataxia, which tended to increase in incidence with age.

Clinical studies of Neurontin® in epilepsy did not include sufficient numbers of subjects aged 65 and over to determine whether they responded differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and dose should be adjusted based on creatinine clearance values in these patients (see CLINICAL PHARMACOLOGY, ADVERSE REACTIONS, and DOSAGE AND ADMINISTRATION sections).

ADVERSE REACTIONS

Postherpetic Neuralgia

The most commonly observed adverse events associated with the use of Neurontin® in adults, not seen at an equivalent frequency among placebo-treated patients, were dizziness, somnolence, and peripheral edema.

In the 2 controlled studies in postherpetic neuralgia, 16% of the 336 patients who received Neurontin® and 9% of the 227 patients who received placebo discontinued treatment because of an adverse event. The adverse events that most frequently led to withdrawal in Neurontin®-treated patients were dizziness, somnolence, and nausea.

Incidence in Controlled Clinical Trials

Table 2 lists treatment-emergent signs and symptoms that occurred in at least 1% of Neurontin®-treated patients with postherpetic neuralgia participating in placebo-controlled trials and that

were numerically more frequent in the Neurontin® group than in the placebo group. Adverse events were usually mild to moderate in intensity.

TABLE 2. Treatment-Emergent Adverse Event Incidence in Controlled Trials in Postherpetic Neuralgia (Events in at least 1% of Neurontin®-Treated Patients and Numerically More Frequent Than in the Placebo Group)

Body System/ Preferred Term	Neurontin® N=336 %	Placebo N=227 %
Body as a Whole		
Asthenia	5.7	4.8
Infection	5.1	3.5
Headache	3.3	3.1
Accidental injury	3.3	1.3
Abdominal pain	2.7	2.6
Digestive System		
Diarrhea	5.7	3.1
Dry mouth	4.8	1.3
Constipation	3.9	1.8
Nausea	3.9	3.1
Vomiting	3.3	1.8
Flatulence	2.1	1.8
Metabolic and Nutritional Disorders		
Peripheral edema	8.3	2.2
Weight gain	1.8	0.0
Hyperglycemia	1.2	0.4
Nervous System		
Dizziness	28.0	7.5
Somnolence	21.4	5.3
Ataxia	3.3	0.0
Thinking abnormal	2.7	0.0
Abnormal gait	1.5	0.0
Incoordination	1.5	0.0
Amnesia	1.2	0.9
Hypesthesia	1.2	0.9
Respiratory System		
Pharyngitis	1.2	0.4
Skin and Appendages		
Rash	1.2	0.9
Special Senses		
Amblyopia[a]	2.7	0.9
Conjunctivitis	1.2	0.0
Diplopia	1.2	0.0
Otitis media	1.2	0.0

[a] Reported as blurred vision

Other events in more than 1% of patients but equally or more frequent in the placebo group included pain, tremor, neuralgia, back pain, dyspepsia, dyspnea, and flu syndrome.

There were no clinically important differences between men and women in the types and incidence of adverse events. Because there were few patients whose race was reported as other than white, there are insufficient data to support a statement regarding the distribution of adverse events by race.

Epilepsy

The most commonly observed adverse events associated with the use of Neurontin® in combination with other antiepileptic drugs in patients >12 years of age, not seen at an equivalent frequency among placebo-treated patients, were somnolence, dizziness, ataxia, fatigue, and nystagmus. The most commonly observed adverse events reported with the use of Neurontin® in combination with other antiepileptic drugs in pediatric patients 3 to 12 years of age, not seen at an equal frequency among placebo-treated patients, were viral infection, fever, nausea and/or vomiting, somnolence, and hostility (see WARNINGS, Neuropsychiatric Adverse Events).

Approximately 7% of the 2074 patients >12 years of age and approximately 7% of the 449 pediatric patients 3 to 12 years of age who received Neurontin® in premarketing clinical trials discontinued treatment because of an adverse event. The adverse events most commonly associated with withdrawal in patients >12 years of age were somnolence (1.2%), ataxia (0.8%), fatigue (0.6%), nausea and/or vomiting (0.6%), and dizziness (0.6%). The adverse events most commonly associated with withdrawal in pediatric patients were emotional lability (1.6%), hostility (1.3%), and hyperkinesia (1.1%).

Incidence in Controlled Clinical Trials

Table 3 lists treatment-emergent signs and symptoms that occurred in at least 1% of Neurontin®-treated patients >12 years of age with epilepsy participating in placebo-controlled trials and were numerically more common in the Neurontin® group. In these studies, either Neurontin® or placebo was added to the patient's current antiepileptic drug therapy. Adverse events were usually mild to moderate in intensity.

The prescriber should be aware that these figures, obtained when Neurontin® was added to concurrent antiepileptic drug therapy, cannot be used to predict the frequency of adverse events in the course of usual medical practice where patient characteristics and other factors may differ from those prevailing during clinical studies. Similarly, the cited frequencies cannot be directly compared with figures obtained from other clinical investigations involving different treatments, uses, or investigators. An inspection of these frequencies, however, does provide the prescribing physician with one basis to estimate the relative contribution of drug and nondrug factors to the adverse event incidences in the population studied.

TABLE 3. Treatment-Emergent Adverse Event Incidence in Controlled Add-On Trials In Patients >12 years of age (Events in at least 1% of Neurontin® patients and numerically more frequent than in the placebo group)

Body System/ Adverse Event	Neurontin®[a] N=543 %	Placebo[a] N=378 %
Body As A Whole		
Fatigue	11.0	5.0
Weight Increase	2.9	1.6
Back Pain	1.8	0.5
Peripheral Edema	1.7	0.5
Cardiovascular		
Vasodilatation	1.1	0.3
Digestive System		
Dyspepsia	2.2	0.5
Mouth or Throat Dry	1.7	0.5
Constipation	1.5	0.8
Dental Abnormalities	1.5	0.3
Increased Appetite	1.1	0.8
Hematologic and Lymphatic Systems		
Leukopenia	1.1	0.5
Musculoskeletal System		
Myalgia	2.0	1.9
Fracture	1.1	0.8
Nervous System		
Somnolence	19.3	8.7
Dizziness	17.1	6.9
Ataxia	12.5	5.6
Nystagmus	8.3	4.0
Tremor	6.8	3.2
Nervousness	2.4	1.9
Dysarthria	2.4	0.5
Amnesia	2.2	0.0
Depression	1.8	1.1
Thinking Abnormal	1.7	1.3
Twitching	1.3	0.5
Coordination Abnormal	1.1	0.3
Respiratory System		
Rhinitis	4.1	3.7
Pharyngitis	2.8	1.6
Coughing	1.8	1.3
Skin and Appendages		
Abrasion	1.3	0.0
Pruritus	1.3	0.5
Urogenital System		
Impotence	1.5	1.1

TABLE 3. Treatment-Emergent Adverse Event Incidence in Controlled Add-On Trials In Patients >12 years of age (Events in at least 1% of Neurontin® patients and numerically more frequent than in the placebo group)

Body System/ Adverse Event	Neurontin®[a] N=543 %	Placebo[a] N=378 %
Special Senses		
Diplopia	5.9	1.9
Amblyopia[b]	4.2	1.1
Laboratory Deviations		
WBC Decreased	1.1	0.5

[a] Plus background antiepileptic drug therapy
[b] Amblyopia was often described as blurred vision.

Other events in more than 1% of patients >12 years of age but equally or more frequent in the placebo group included: headache, viral infection, fever, nausea and/or vomiting, abdominal pain, diarrhea, convulsions, confusion, insomnia, emotional lability, rash, acne.

Among the treatment-emergent adverse events occurring at an incidence of at least 10% of Neurontin®-treated patients, somnolence and ataxia appeared to exhibit a positive dose-response relationship.

The overall incidence of adverse events and the types of adverse events seen were similar among men and women treated with Neurontin®. The incidence of adverse events increased slightly with increasing age in patients treated with either Neurontin® or placebo. Because only 3% of patients (28/921) in placebo-controlled studies were identified as nonwhite (black or other), there are insufficient data to support a statement regarding the distribution of adverse events by race.

Table 4 lists treatment-emergent signs and symptoms that occurred in at least 2% of Neurontin®-treated patients age 3 to 12 years of age with epilepsy participating in placebo-controlled trials and were numerically more common in the Neurontin® group. Adverse events were usually mild to moderate in intensity.

TABLE 4. Treatment-Emergent Adverse Event Incidence in Pediatric Patients Age 3 to 12 Years in a Controlled Add-On Trial (Events in at least 2% of Neurontin® patients and numerically more frequent than in the placebo group)

Body System/ Adverse Event	Neurontin®[a] N=119 %	Placebo[a] N=128 %
Body As A Whole		
Viral Infection	10.9	3.1
Fever	10.1	3.1
Weight Increase	3.4	0.8
Fatigue	3.4	1.6
Digestive System		
Nausea and/or Vomiting	8.4	7.0

TABLE 4. Treatment-Emergent Adverse Event Incidence in Pediatric Patients Age 3 to 12 Years in a Controlled Add-On Trial (Events in at least 2% of Neurontin® patients and numerically more frequent than in the placebo group)

Body System/ Adverse Event	Neurontin®[a] N=119 %	Placebo[a] N=128 %
Nervous System		
Somnolence	8.4	4.7
Hostility	7.6	2.3
Emotional Lability	4.2	1.6
Dizziness	2.5	1.6
Hyperkinesia	2.5	0.8
Respiratory System		
Bronchitis	3.4	0.8
Respiratory Infection	2.5	0.8

[a] Plus background antiepileptic drug therapy

Other events in more than 2% of pediatric patients 3 to 12 years of age but equally or more frequent in the placebo group included: pharyngitis, upper respiratory infection, headache, rhinitis, convulsions, diarrhea, anorexia, coughing, and otitis media.

Other Adverse Events Observed During All Clinical Trials

Clinical Trials in Adults and Adolescents (Except Clinical Trials in Neuropathic Pain)

Neurontin® has been administered to 2074 patients >12 years of age during all adjunctive therapy clinical trials (except clinical trials in patients with neuropathic pain), only some of which were placebo-controlled. During these trials, all adverse events were recorded by the clinical investigators using terminology of their own choosing. To provide a meaningful estimate of the proportion of individuals having adverse events, similar types of events were grouped into a smaller number of standardized categories using modified COSTART dictionary terminology. These categories are used in the listing below. The frequencies presented represent the proportion of the 2074 patients >12 years of age exposed to Neurontin® who experienced an event of the type cited on at least one occasion while receiving Neurontin®. All reported events are included except those already listed in Table 3, those too general to be informative, and those not reasonably associated with the use of the drug.

Events are further classified within body system categories and enumerated in order of decreasing frequency using the following definitions: frequent adverse events are defined as those occurring in at least 1/100 patients; infrequent adverse events are those occurring in 1/100 to 1/1000 patients; rare events are those occurring in fewer than 1/1000 patients.

Body As A Whole: *Frequent:* asthenia, malaise, face edema; *Infrequent:* allergy, generalized edema, weight decrease, chill; *Rare:* strange feelings, lassitude, alcohol intolerance, hangover effect.

Cardiovascular System: *Frequent:* hypertension; *Infrequent:* hypotension, angina pectoris, peripheral vascular disorder, palpitation, tachycardia, migraine, murmur; *Rare:* atrial fibrillation, heart failure, thrombophlebitis, deep thrombophlebitis, myocardial infarction, cerebrovascular accident, pulmonary thrombosis, ventricular extrasystoles, bradycardia, premature atrial contraction, pericardial rub, heart block, pulmonary embolus, hyperlipidemia, hypercholesterolemia, pericardial effusion, pericarditis.

Digestive System: *Frequent:* anorexia, flatulence, gingivitis; *Infrequent:* glossitis, gum hemorrhage, thirst, stomatitis, increased salivation, gastroenteritis, hemorrhoids, bloody stools, fecal incontinence, hepatomegaly; *Rare:* dysphagia, eructation, pancreatitis, peptic ulcer, colitis, blisters in mouth, tooth discolor, perlèche, salivary gland enlarged, lip hemorrhage, esophagitis, hiatal hernia, hematemesis, proctitis, irritable bowel syndrome, rectal hemorrhage, esophageal spasm.

Endocrine System: *Rare:* hyperthyroid, hypothyroid, goiter, hypoestrogen, ovarian failure, epididymitis, swollen testicle, cushingoid appearance.

Hematologic and Lymphatic System: *Frequent:* purpura most often described as bruises resulting from physical trauma; *Infrequent:* anemia, thrombocytopenia, lymphadenopathy; *Rare:* WBC count increased, lymphocytosis, non-Hodgkin's lymphoma, bleeding time increased.

Musculoskeletal System: *Frequent:* arthralgia; *Infrequent:* tendinitis, arthritis, joint stiffness, joint swelling, positive Romberg test; *Rare:* costochondritis, osteoporosis, bursitis, contracture.

Nervous System: *Frequent:* vertigo, hyperkinesia, paresthesia, decreased or absent reflexes, increased reflexes, anxiety, hostility; *Infrequent:* CNS tumors, syncope, dreaming abnormal, aphasia, hypesthesia, intracranial hemorrhage, hypotonia, dysesthesia, paresis, dystonia, hemiplegia, facial paralysis, stupor, cerebellar dysfunction, positive Babinski sign, decreased position sense, subdural hematoma, apathy, hallucination, decrease or loss of libido, agitation, paranoia, depersonalization, euphoria, feeling high, doped-up sensation, suicidal, psychosis; *Rare:* choreoathetosis, orofacial dyskinesia, encephalopathy, nerve palsy, personality disorder, increased libido, subdued temperament, apraxia, fine motor control disorder, meningismus, local myoclonus, hyperesthesia, hypokinesia, mania, neurosis, hysteria, antisocial reaction, suicide gesture.

Respiratory System: *Frequent:* pneumonia; *Infrequent:* epistaxis, dyspnea, apnea; *Rare:* mucositis, aspiration pneumonia, hyperventilation, hiccup, laryngitis, nasal obstruction, snoring, bronchospasm, hypoventilation, lung edema.

Dermatological: *Infrequent:* alopecia, eczema, dry skin, increased sweating, urticaria, hirsutism, seborrhea, cyst, herpes simplex; *Rare:* herpes zoster, skin discolor, skin papules, photosensitive reaction, leg ulcer, scalp seborrhea, psoriasis, desquamation, maceration, skin nodules, subcutaneous nodule, melanosis, skin necrosis, local swelling.

Urogenital System: *Infrequent:* hematuria, dysuria, urination frequency, cystitis, urinary retention, urinary incontinence, vaginal hemorrhage, amenorrhea, dysmenorrhea, menorrhagia, breast cancer, unable to climax, ejaculation abnormal; *Rare:* kidney pain, leukorrhea, pruritus genital, renal stone, acute renal failure, anuria, glycosuria, nephrosis, nocturia, pyuria, urination urgency, vaginal pain, breast pain, testicle pain.

Special Senses: *Frequent:* abnormal vision; *Infrequent:* cataract, conjunctivitis, eyes dry, eye pain, visual field defect, photophobia, bilateral or unilateral ptosis, eye hemorrhage, hordeolum,

hearing loss, earache, tinnitus, inner ear infection, otitis, taste loss, unusual taste, eye twitching, ear fullness; *Rare:* eye itching, abnormal accommodation, perforated ear drum, sensitivity to noise, eye focusing problem, watery eyes, retinopathy, glaucoma, iritis, corneal disorders, lacrimal dysfunction, degenerative eye changes, blindness, retinal degeneration, miosis, chorioretinitis, strabismus, eustachian tube dysfunction, labyrinthitis, otitis externa, odd smell.

Clinical trials in Pediatric Patients With Epilepsy

Adverse events occurring during epilepsy clinical trials in 449 pediatric patients 3 to 12 years of age treated with gabapentin that were not reported in adjunctive trials in adults are:

Body as a Whole: dehydration, infectious mononucleosis

Digestive System: hepatitis

Hemic and Lymphatic System: coagulation defect

Nervous System: aura disappeared, occipital neuralgia

Psychobiologic Function: sleepwalking

Respiratory System: pseudocroup, hoarseness

Clinical Trials in Adults With Neuropathic Pain of Various Etiologies

Safety information was obtained in 1173 patients during double-blind and open-label clinical trials including neuropathic pain conditions for which efficacy has not been demonstrated. Adverse events reported by investigators were grouped into standardized categories using modified COSTART IV terminology. Listed below are all reported events except those already listed in Table 2 and those not reasonably associated with the use of the drug.

Events are further classified within body system categories and enumerated in order of decreasing frequency using the following definitions: frequent adverse events are defined as those occurring in at least 1/100 patients; infrequent adverse events are those occurring in 1/100 to 1/1000 patients; rare events are those occurring in fewer than 1/1000 patients.

Body as a Whole: *Infrequent:* chest pain, cellulitis, malaise, neck pain, face edema, allergic reaction, abscess, chills, chills and fever, mucous membrane disorder; *Rare:* body odor, cyst, fever, hernia, abnormal BUN value, lump in neck, pelvic pain, sepsis, viral infection.

Cardiovascular System: *Infrequent:* hypertension, syncope, palpitation, migraine, hypotension, peripheral vascular disorder, cardiovascular disorder, cerebrovascular accident, congestive heart failure, myocardial infarction, vasodilatation; *Rare:* angina pectoris, heart failure, increased capillary fragility, phlebitis, thrombophlebitis, varicose vein.

Digestive System: *Infrequent:* gastroenteritis, increased appetite, gastrointestinal disorder, oral moniliasis, gastritis, tongue disorder, thirst, tooth disorder, abnormal stools, anorexia, liver function tests abnormal, periodontal abscess; *Rare:* cholecystitis, cholelithiasis, duodenal ulcer, fecal incontinence, gamma glutamyl transpeptidase increased, gingivitis, intestinal obstruction, intestinal ulcer, melena, mouth ulceration, rectal disorder, rectal hemorrhage, stomatitis.

Endocrine System: *Infrequent:* diabetes mellitus.

Hemic and Lymphatic System: *Infrequent:* ecchymosis, anemia; *Rare:* lymphadenopathy, lymphoma-like reaction, prothrombin decreased.

Metabolic and Nutritional: *Infrequent:* edema, gout, hypoglycemia, weight loss; *Rare:* alkaline phosphatase increased, diabetic ketoacidosis, lactic dehydrogenase increased.

Musculoskeletal: *Infrequent:* arthritis, arthralgia, myalgia, arthrosis, leg cramps, myasthenia; *Rare:* shin bone pain, joint disorder, tendon disorder.

Nervous System: *Frequent:* confusion, depression; *Infrequent:* vertigo, nervousness, paresthesia, insomnia, neuropathy, libido decreased, anxiety, depersonalization, reflexes decreased, speech disorder, abnormal dreams, dysarthria, emotional lability, nystagmus, stupor, circumoral paresthesia, euphoria, hyperesthesia, hypokinesia; *Rare:* agitation, hypertonia, libido increased, movement disorder, myoclonus, vestibular disorder.

Respiratory System: *Infrequent:* cough increased, bronchitis, rhinitis, sinusitis, pneumonia, asthma, lung disorder, epistaxis; *Rare:* hemoptysis, voice alteration.

Skin and Appendages: *Infrequent:* pruritus, skin ulcer, dry skin, herpes zoster, skin disorder, fungal dermatitis, furunculosis, herpes simplex, psoriasis, sweating, urticaria, vesiculobullous rash; *Rare:* acne, hair disorder, maculopapular rash, nail disorder, skin carcinoma, skin discoloration, skin hypertrophy.

Special Senses: *Infrequent:* abnormal vision, ear pain, eye disorder, taste perversion, deafness; *Rare:* conjunctival hyperemia, diabetic retinopathy, eye pain, fundi with microhemorrhage, retinal vein thrombosis, taste loss.

Urogenital System: *Infrequent:* urinary tract infection, dysuria, impotence, urinary incontinence, vaginal moniliasis, breast pain, menstrual disorder, polyuria, urinary retention; *Rare:* cystitis, ejaculation abnormal, swollen penis, gynecomastia, nocturia, pyelonephritis, swollen scrotum, urinary frequency, urinary urgency, urine abnormality.

Postmarketing and Other Experience

In addition to the adverse experiences reported during clinical testing of Neurontin®, the following adverse experiences have been reported in patients receiving marketed Neurontin®. These adverse experiences have not been listed above and data are insufficient to support an estimate of their incidence or to establish causation. The listing is alphabetized: angioedema, blood glucose fluctuation, erythema multiforme, elevated liver function tests, fever, hyponatremia, jaundice, movement disorder such as dyskinesia, Stevens-Johnson syndrome.

Adverse events following the abrupt discontinuation of gabapentin have also been reported. The most frequently reported events were anxiety, insomnia, nausea, pain and sweating.

DRUG ABUSE AND DEPENDENCE

The abuse and dependence potential of Neurontin® has not been evaluated in human studies.

OVERDOSAGE

A lethal dose of gabapentin was not identified in mice and rats receiving single oral doses as high as 8000 mg/kg. Signs of acute toxicity in animals included ataxia, labored breathing, ptosis, sedation, hypoactivity, or excitation.

Acute oral overdoses of Neurontin® up to 49 grams have been reported. In these cases, double vision, slurred speech, drowsiness, lethargy and diarrhea were observed. All patients recovered with supportive care.

Gabapentin can be removed by hemodialysis. Although hemodialysis has not been performed in the few overdose cases reported, it may be indicated by the patient's clinical state or in patients with significant renal impairment.

DOSAGE AND ADMINISTRATION

Neurontin® is given orally with or without food.

If Neurontin® dose is reduced, discontinued or substituted with an alternative medication, this should be done gradually over a minimum of 1 week.

Postherpetic Neuralgia

In adults with postherpetic neuralgia, Neurontin® therapy may be initiated as a single 300-mg dose on Day 1, 600 mg/day on Day 2 (divided BID), and 900 mg/day on Day 3 (divided TID). The dose can subsequently be titrated up as needed for pain relief to a daily dose of 1800 mg (divided TID). In clinical studies, efficacy was demonstrated over a range of doses from 1800 mg/day to 3600 mg/day with comparable effects across the dose range. Additional benefit of using doses greater than 1800 mg/day was not demonstrated.

Epilepsy

Neurontin® is recommended for add-on therapy in patients 3 years of age and older. Effectiveness in pediatric patients below the age of 3 years has not been established.

Patients >12 years of age: The effective dose of Neurontin® is 900 to 1800 mg/day and given in divided doses (three times a day) using 300 or 400 mg capsules, or 600 or 800 mg tablets. The starting dose is 300 mg three times a day. If necessary, the dose may be increased using 300 or 400 mg capsules, or 600 or 800 mg tablets three times a day up to 1800 mg/day. Dosages up to 2400 mg/day have been well tolerated in long-term clinical studies. Doses of 3600 mg/day have also been administered to a small number of patients for a relatively short duration, and have been well tolerated. The maximum time between doses in the TID schedule should not exceed 12 hours.

Pediatric Patients Age 3–12 years: The starting dose should range from 10-15 mg/kg/day in 3 divided doses, and the effective dose reached by upward titration over a period of approximately 3 days. The effective dose of Neurontin® in patients 5 years of age and older is 25–35 mg/kg/day and given in divided doses (three times a day). The effective dose in pediatric patients ages 3 and 4 years is 40 mg/kg/day and given in divided doses (three times a day) (see CLINICAL PHARMACOLOGY, Pediatrics.) Neurontin® may be administered as the oral solution, capsule, or tablet, or using combinations of these formulations. Dosages up to 50 mg/kg/day have been well-tolerated in a long-term clinical study. The maximum time interval between doses should not exceed 12 hours.

It is not necessary to monitor gabapentin plasma concentrations to optimize Neurontin® therapy. Further, because there are no significant pharmacokinetic interactions among Neurontin® and

other commonly used antiepileptic drugs, the addition of Neurontin® does not alter the plasma levels of these drugs appreciably.

If Neurontin® is discontinued and/or an alternate anticonvulsant medication is added to the therapy, this should be done gradually over a minimum of 1 week.

Dosage in Renal Impairment

Creatinine clearance is difficult to measure in outpatients. In patients with stable renal function, creatinine clearance (C_{Cr}) can be reasonably well estimated using the equation of Cockcroft and Gault:

$$\text{for females } C_{Cr}=(0.85)(140\text{-age})(\text{weight})/[(72)(S_{Cr})]$$
$$\text{for males } C_{Cr}=(140\text{-age})(\text{weight})/[(72)(S_{Cr})]$$

where age is in years, weight is in kilograms and S_{Cr} is serum creatinine in mg/dL.

Dosage adjustment in patients ≥12 years of age with compromised renal function or undergoing hemodialysis is recommended as follows (see dosing recommendations above for effective doses in each indication).

TABLE 5. Neurontin® Dosage Based on Renal Function

Renal Function Creatinine Clearance (mL/min)	Total Daily Dose Range (mg/day)	Dose Regimen (mg)				
≥60	900-3600	300 TID	400 TID	600 TID	800 TID	1200 TID
>30-59	400-1400	200 BID	300 BID	400 BID	500 BID	700 BID
>15-29	200-700	200 QD	300 QD	400 QD	500 QD	700 QD
15[a]	100-300	100 QD	125 QD	150 QD	200 QD	300 QD
		Post-Hemodialysis Supplemental Dose (mg)[b]				
Hemodialysis		125[b]	150[b]	200[b]	250[b]	350[b]

[a] For patients with creatinine clearance <15 mL/min, reduce daily dose in proportion to creatinine clearance (e.g., patients with a creatinine clearance of 7.5 mL/min should receive one-half the daily dose that patients with a creatinine clearance of 15 mL/min receive).

[b] Patients on hemodialysis should receive maintenance doses based on estimates of creatinine clearance as indicated in the upper portion of the table and a supplemental post-hemodialysis dose administered after each 4 hours of hemodialysis as indicated in the lower portion of the table.

The use of Neurontin® in patients <12 years of age with compromised renal function has not been studied.

Dosage in Elderly

Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and dose should be adjusted based on creatinine clearance values in these patients.

HOW SUPPLIED

Neurontin® (gabapentin) capsules, tablets and oral solution are supplied as follows:

100 mg capsules;

White hard gelatin capsules printed with "PD" on one side and "Neurontin®/100 mg" on the other; available in:
Bottles of 100: N 0071-0803-24
Unit dose 50's: N 0071-0803-40

300 mg capsules;

Yellow hard gelatin capsules printed with "PD" on one side and "Neurontin®/300 mg" on the other; available in:
Bottles of 100: N 0071-0805-24
Unit dose 50's: N 0071-0805-40

400 mg capsules;

Orange hard gelatin capsules printed with "PD" on one side and "Neurontin®/400 mg" on the other; available in:
Bottles of 100: N 0071-0806-24
Unit dose 50's: N 0071-0806-40

600 mg tablets;

White elliptical film-coated scored tablets debossed with "NT" and "16" on one side; available in:
Bottles of 100: N 0071-0513-24

800 mg tablets;

White elliptical film-coated scored tablets debossed with "NT" and "26" on one side; available in:
Bottles of 100: N 0071-0401-24

250 mg/5 mL oral solution;

Clear colorless to slightly yellow solution; each 5 mL of oral solution contains 250 mg of gabapentin; available in:
Bottles containing 470 mL: N0071-2012-23

Storage (Capsules)

Store at 25°C (77°F); excursions permitted to 15° - 30°C (59° - 86°F) [see USP Controlled Room Temperature].

Storage (Tablets)

Store at 25°C (77°F); excursions permitted to 15° - 30°C (59° - 86°F) [see USP Controlled Room Temperature].

Storage (Oral Solution)

Store refrigerated, 2°-8°C (36°-46°F)

Rx only

Revised September 2003

Capsules and Tablets:

Manufactured by:
Pfizer Pharmaceuticals, Ltd.
Vega Baja, PR 00694

Oral Solution:

Manufactured for:
Pfizer Pharmaceuticals, Ltd.
Vega Baja, PR 00694

Distributed by:

Parke-Davis
Division of Pfizer Inc, NY, NY 10017

75-5800-00-4

Attachment 2
Completed Suicide Reports

Control Number. 3551076

Patient Information

Age	Sex	Location	Date of Birth	Year of Receipt	Month of receipt	Date of receipt	Event Date	Manufacturer Date.
38	M			2000	08	8/15/2000	02/22/2000	08/02/2000

Report Information

Source Code	Manufacturer	Manufacturer Control Num	Image ID	Report Type	Case Number	F/U Status	Seq
	PARKE DAVIS PHARMACEUTICALS	032-0945-M0000010	3551076-5	EX	3454425	F	1

Drug Information SubForm

Drug	Suspect Status	Dosage	Units	Administration	Start Date	Stop Date
NEURONTIN	PS	ORAL		ORAL		
CARBAMAZEPINE	SS					
(LOPRAZOLAM)	SS					
SERTRALIN (SERTRALINE)	C					
(PERICIAZIN (PERICIAZINE)	C					
(PROTHIPENDYL) (PROTHIPENDYL)	C					

Outcome

Outcome
DE

Source

Source
FGN
HP
SDY

Reactions Referenced

COSTART/MedDRA	Onset
COMPLETED SUICIDE	
NON-ACCIDENTAL OVERDOSE	

Neurontin Indications:

Control Number 3661327

Patient Information

Age	Sex	Location	Date of Birth	Year of Receipt	Month of receipt	Date of receipt	Event Date	Manufacturer Date
	M			2001	02	2/5/2001		01/22/2001

Report Information

Source Code	Manufacturer	Manufacturer Control Num	Image ID	Report Type	Case Number	F/U Status:	Seq
	PARKE DAVIS PHARMACEUTICALS	001-0945-M0100100	3661327-4	EX	3606736	I	

Drug Information SubForm

Drug	Suspect Status	Dosage	Units	Administration	Start Date	Stop Date
NEURONTIN	PS					
UNSPECIFIED MEDICATIONS	SS					

Outcome

Outcome
DE

Source

Source
CSM
HP

Reactions Referenced

COSTART/MedDRA	Onset
COMPLETED SUICIDE	

Neurontin Indications:

Control Number 3915659

Patient Information

Age	Sex	Location	Date of Birth	Year of Receipt	Month of receipt	Date of receipt	Event Date	Manufacturer Date
	M					5/13/2002	4/5/2002	5/1/2002

Report Information

Source Code	Manufacturer	Manufacturer Control Num	Image ID	Report Type	Case Number	F/U Status	Seq
	PFIZER PHARMACEUTICALS	A208483	3915659-2	EX	3789050	F	1

Drug Information SubForm

Drug	Suspect Status	Dosage	Units	Administration	Start Date	Stop Date
ZOLOFT	PS				4/5/2002	4/9/2002
GABAPENTIN	SS					4/9/2002
OXYCONTIN	SS					

Outcome

Outcome
DE

Source

Source
CSM

Reactions Referenced

COSTART/MedDRA	Onset
ABDOMINAL PAIN NOS	
ABDOMINAL PAIN UPPER	
COMPLETED SUICIDE	
DRUG INEFFECTIVE	
GASTROINTESTINAL DISORDER N	
GUN SHOT WOUND	
MARKEDLY REDUCED DIETARY IN	
MEDICATION ERROR	

Neurontin Indications

Indication
PERIPHERAL NEUROPATHY NOS

Control Number 3915941

Patient Information

Age	Sex	Location	Date of Birth	Year of Receipt	Month of receipt	Date of receipt	Event Date	Manufacturer Date
	M					5/13/2002	1/1/2001	5/1/2002

Report Information

Source Code	Manufacturer	Manufacturer Control Num	Image ID	Report Type	Case Number	F/U Status	Seq:
	PFIZER PHARMACEUTICALS	001-0945-M0200490	3915941-8	EX	3789052	F	1

Drug Information SubForm

Drug	Suspect Status	Dosage	Units	Administration	Start Date	Stop Date
NEURONTIN	PS					4/9/2002
SERTRALINE HCL	SS	75 MG, (DAILY)			4/5/2002	4/9/2002
OXYCODONE HCL	SS					

Outcome

Outcome
DE
OT

Source

Source
CSM

Reactions Referenced

COSTART/MedDRA	Onset
ABDOMINAL PAIN NOS	
COMPLETED SUICIDE	
EATING DISORDER NEC	
GASTROINTESTINAL DISORDER N	
GUN SHOT WOUND	
IDIOSYNCRATIC DRUG REACTION	

Neurontin Indications

Indication
PERIPHERAL NEUROPATHY NOS

Control Number 3977792

Patient Information

Age	Sex	Location	Date of Birth	Year of Receipt	Month of receipt	Date of receipt	Event Date	Manufacturer Date
72	M					9/19/2002	8/1/2002	9/6/2002

Report Information

Source Code	Manufacturer	Manufacturer Control Num	Image ID	Report Type	Case Number	F/U Status	Seq
	PFIZER PHARMACEUTICALS	2002057053	3977792-9	EX	3843112	I	

Drug Information SubForm

Drug	Suspect Status	Dosage	Units	Administration	Start Date	Stop Date
GABAPENTIN	PS	1200 MG (400 MG, TID),		ORAL	3/1/2001	

Outcome

Outcome
DE
LT
OT

Source

Source
CR
FGN
HP

Reactions Referenced

COSTART/MedDRA	Onset
COMPLETED SUICIDE	

Neurontin Indications

Indication
PERIPHERAL NEUROPATHY NOS

Control Number 3992628

Patient Information

Age	Sex	Location	Date of Birth	Year of Receipt	Month of receipt	Date of receipt	Event Date	Manufacturer Date
	M					10/11/2002	7/1/2002	10/1/2002

Report Information

Source Code	Manufacturer	Manufacturer Control Num	Image ID	Report Type	Case Number	F/U Status	Seq
	PFIZER PHARMACEUTICALS	2002060656	3992628-8	EX	3853840	I	

Drug Information SubForm

Drug	Suspect Status	Dosage	Units	Administration	Start Date	Stop Date
NEURONTIN	PS				1/1/2002	1/1/2002
ETHANOL	SS				1/1/2002	1/1/2002
UNSPECIFIED ANTIDEPRESSANTS	C					

Outcome

Outcome
DE

Source

Source
CR
FGN
HP

Reactions Referenced

COSTART/MedDRA	Onset
COMPLETED SUICIDE	

Neurontin Indications:

Report Information

Source Code	Manufacturer	Manufacturer Control Num	Image ID	Report Type	Case Number	F/U Status	Seq
	PFIZER PHARMACEUTICALS	2002064868	4009078-0	EX	3864545	I	

Drug Information SubForm

Drug	Suspect Status	Dosage	Units	Administration	Start Date	Stop Date
NEURONTIN	PS					

Outcome

Outcome
DE
OT

Source

Source
CSM

Reactions Referenced

COSTART/MedDRA	Onset
COMPLETED SUICIDE	

Neurontin Indications.

NEURONTIN	PS				

Outcome	Source	Reactions Referenced		Neurontin Indications
Outcome	Source	COSTART/MedDRA	Onset	Indication
DE	CSM	COMPLETED SUICIDE		BIPOLAR DISORDER

Control Number 4055087

Patient Information

Age	Sex	Location	Date of Birth	Year of Receipt	Month of receipt	Date of receipt	Event Date	Manufacturer Date
50				2003	2	2/10/2003		12/12/2002

Report Information

Source Code	Manufacturer	Manufacturer Control Num	Image ID	Report Type	Case Number	F/U Status	Seq
	PFIZER PHARMACEUTICALS	2003003075	4055087-5	EX	3924377	I	

Drug Information SubForm

38	2003	2	2/10/2003	Manufacturer Date 12/12/2002	

Report Information

Source Code	Manufacturer	Manufacturer Control Num	Image ID	Report Type	Case Number	F/U Status	Seq
	PFIZER PHARMACEUTICALS	2003003076	4055102-9	EX	3903986	1	

Drug Information SubForm

Drug	Suspect Status		Dosage	Units	Administration	Start Date	Stop Date
GABAPENTIN	PS	ORAL			ORAL		
AMOXAPINE	SS	ORAL			ORAL		
QUETIAPINE	SS	ORAL			ORAL		

Outcome

Outcome
DE

Source

Source
HP
LIT

Reactions Referenced

COSTART/MedDRA	Onset
COMPLETED SUICIDE	
NON-ACCIDENTAL OVERDOSE	

Neurontin Indications

Control Number 4103106

Patient Information

Age	Sex	Location	Date of Birth	Year of Receipt	Month of receipt	Date of receipt	Event Date	Manufacturer Date
21				2003	4	4/25/2003		4/14/2003

Report Information

Source Code	Manufacturer	Manufacturer Control Num	Image ID	Report Type	Case Number	F/U Status	Seq.
	WWS PFIZER PHARMACEUTICALS	2003016415	4103106-X	EX	3941439	I	

Drug Information SubForm

Drug	Suspect Status	Dosage	Units	Administration	Start Date	Stop Date
GABAPENTIN	PS	ORAL		ORAL		
HALOPERIDOL	SS	ORAL		ORAL		
BENZATROPINE MESILATE (BENZATROPINE	SS	ILL-DEFINED DISORDER				

Outcome

Outcome
DE

Source

Source
HP
LIT

Reactions Referenced

COSTART/MedDRA	Onset
COMPLETED SUICIDE	

Neurontin Indications.

Indication
ILL-DEFINED DISORDER NOS

Control Number 4103108

Patient Information

Age	Sex	Location	Date of Birth	Year of Receipt	Month of receipt	Date of receipt	Event Date	Manufacturer Date
11	F			2003	4	4/25/2003		4/14/2003

Report Information

Source Code	Manufacturer	Manufacturer Control Num	Image ID	Report Type	Case Number	F/U Status	Seq
	WWS PFIZER PHARMACEUTICALS	2003016399	4103108-3	EX	3941441	1	

Drug Information SubForm

Drug	Suspect Status	Dosage	Units	Administration	Start Date	Stop Date
GABAPENTIN	PS	(ONCE), ORAL		ORAL		
NORTRIPTYLINE HCL	SS	6000 MG (ONCE), ORAL		ORAL		

Outcome

Outcome
DE
HO
OT

Source

Source
HP
LIT

Reactions Referenced

COSTART/MedDRA	Onset
ARRHYTHMIA NOS	
BLOOD PH INCREASED	
BLOOD POTASSIUM DECREASED	
BLOOD SODIUM INCREASED	
CARDIAC ARREST	
COMPLETED SUICIDE	
CONVULSIONS NOS	
DISSEMINATED INTRAVASCULAR C	
HYPOGLYCAEMIA NOS	
HYPOTENSION NOS	
INTESTINAL ISCHAEMIA	
INTESTINAL PERFORATION NOS	
LOSS OF CONSCIOUSNESS	
OLIGURIA	
SEPSIS NOS	
TACHYCARDIA NOS	

Neurontin Indications

Indication
ILL-DEFINED DISORDER NOS

Control Number 4103109

Patient Information

Age	Sex	Location	Date of Birth	Year of Receipt	Month of receipt	Date of receipt	Event Date	Manufacturer Date
36				2003	4	4/25/2003		4/14/2003

Report Information

Source Code	Manufacturer	Manufacturer Control Num	Image ID	Report Type	Case Number	F/U Status:	Seq
	WWS PFIZER PHARMACEUTICALS	2003016396	4103109-5	EX	3941427	I	

Drug Information SubForm

Drug	Suspect Status		Dosage	Units	Administration	Start Date	Stop Date
GABAPENTIN	PS	ORAL			ORAL		
OXYCODONE (OXYCODONE)	SS	ORAL			ORAL		
PAROXETINE HCL	SS	ORAL			ORAL		

Outcome

Outcome
DE
OT

Source

Source
HP
LIT

Reactions Referenced

COSTART/MedDRA	Onset
CARDIO-RESPIRATORY ARREST	
COMPLETED SUICIDE	

Neurontin Indications:

Indication
ILL-DEFINED DISORDER NOS

Control Number 4103110

Patient Information

Age	Sex	Location	Date of Birth	Year of Receipt	Month of receipt	Date of receipt	Event Date	Manufacturer Date
38				2003	4	4/25/2003		4/14/2003

Report Information

Source Code	Manufacturer	Manufacturer Control Num	Image ID	Report Type	Case Number	F/U Status	Seq
	WWS PFIZER PHARMACEUTICALS	2003016417	4103110-1	EX	3941429	1	

Drug Information SubForm

Drug	Suspect Status	Dosage	Units	Administration	Start Date	Stop Date
GABAPENTIN	PS	ORAL		ORAL		
ZOLPIDEM TARTRATE	SS	ORAL		ORAL		

Outcome

Outcome
DE

Source

Source
HP
LIT

Reactions Referenced

COSTART/MedDRA	Onset
COMPLETED SUICIDE	

Neurontin Indications.

Indication
ILL-DEFINED DISORDER NOS

Control Number 4103119

Patient Information

Age	Sex	Location	Date of Birth	Year of Receipt	Month of receipt	Date of receipt	Event Date	Manufacturer Date
19				2003	4	4/25/2003		4/14/2003

Report Information

Source Code	Manufacturer	Manufacturer Control Num	Image ID	Report Type	Case Number.	F/U Status.	Seq
	WWS PFIZER PHARMACEUTICALS	2003016395	4103119-8	EX	3941433	I	

Drug Information SubForm

Drug	Suspect Status		Dosage	Units	Administration	Start Date	Stop Date
GABAPENTIN	PS	ORAL			ORAL		
VALPROIC ACID	SS	ORAL			ORAL		
OLANZAPINE	SS	ORAL			ORAL		
ALL OTHER THERAPEUTIC PRODUCTS	SS	ORAL			ORAL		

Outcome

Outcome
DE

Source

Source
HP
LIT

Reactions Referenced

COSTART/MedDRA	Onset
COMPLETED SUICIDE	
DRUG LEVEL NOS INCREASED	

Neurontin Indications

Indication
ILL-DEFINED DISORDER NOS

Control Number 4103162

Patient Information

Age	Sex	Location	Date of Birth	Year of Receipt	Month of receipt	Date of receipt	Event Date	Manufacturer Date
54				2003	4	4/25/2003		4/14/2003

Report Information

Source Code	Manufacturer	Manufacturer Control Num	Image ID	Report Type	Case Number	F/U Status	Seq.
	PFIZER PHARMACEUTICALS	2003016394	4103162-9	EX	3941490	I	

Drug Information SubForm

Drug	Suspect Status	Dosage	Units	Administration	Start Date	Stop Date
GABAPENTIN	PS	ORAL		ORAL		

Outcome

Outcome
DE

Source

Source
HP
LIT

Reactions Referenced

COSTART/MedDRA	Onset
COMPLETED SUICIDE	

Neurontin Indications

Indication
ILL-DEFINED DISORDER NOS

Control Number 4103187

Patient Information

Age	Sex	Location	Date of Birth	Year of Receipt	Month of receipt	Date of receipt	Event Date	Manufacturer Date
54				2003	4	4/25/2003		4/14/2003

Report Information

Source Code	Manufacturer	Manufacturer Control Num	Image ID	Report Type	Case Number	F/U Status	Seq
	PFIZER PHARMACEUTICALS	2003016397	4103187-3	EX	3941496	I	

Drug Information SubForm

Drug	Suspect Status		Dosage	Units	Administration	Start Date	Stop Date
GABAPENTIN	PS	ORAL			ORAL		
AMITRIPTYLINE HYDROCHLORIDE	SS	ORAL			ORAL		
ZOLPIDEM TARTRATE	SS	ORAL			ORAL		
ALL OTHER THERAPEUTIC PRODUCTS	SS	ORAL			ORAL		

Outcome

Outcome
DE

Source

Source
HP
LIT

Reactions Referenced

COSTART/MedDRA	Onset
COMPLETED SUICIDE	

Neurontin Indications

Indication
ILL-DEFINED DISORDER NOS

Control Number 4103190

Patient Information

Age	Sex	Location	Date of Birth	Year of Receipt	Month of receipt	Date of receipt	Event Date	Manufacturer Date
52				2003	4	4/25/2003		4/14/2003

Report Information

Source Code	Manufacturer	Manufacturer Control Num	Image ID	Report Type	Case Number	F/U Status	Seq
	PFIZER PHARMACEUTICALS	2003016387	4103190-3	EX	3941503	I	

Drug Information SubForm

Drug	Suspect Status		Dosage	Units	Administration	Start Date	Stop Date
GABAPENTIN	PS	ORAL			ORAL		
GALENIC /PARACETAMOL/CODEINE/ (CODEI	SS	ORAL			ORAL		
FOSINOPRIL SODIUM	SS	ORAL			ORAL		
ALL OTHER THERAPEUTIC PRODUCTS	C	ORAL					

Outcome

Outcome
DE

Source

Source
HP
LIT

Reactions Referenced

COSTART/MedDRA	Onset
COMPLETED SUICIDE	

Neurontin Indications

Indication
ILL-DEFINED DISORDER NOS

Control Number 4105635

Patient Information

Age	Sex	Location	Date of Birth	Year of Receipt	Month of receipt	Date of receipt	Event Date	Manufacturer Date
	M			2003	4	4/30/2003	1/1/2003	4/17/2003

Report Information

Source Code	Manufacturer	Manufacturer Control Num	Image ID	Report Type	Case Number	F/U Status	Seq
	WWS PFIZER PHARMACEUTICALS	2003017239	4105635-1	EX	3943540	I	

Drug Information SubForm

Drug	Suspect Status	Dosage	Units	Administration	Start Date	Stop Date
NEURONTIN	PS	900 MG (300 , THREE TI		ORAL		
ALPRAZOLAM	C					
ATENOLOL	C					
ALLOPURINOL	C					
FUROSEMIDE	C					
MINOXIDIL	C					

Outcome

Outcome
DE

Source

Source
HP

Reactions Referenced

COSTART/MedDRA	Onset
COMPLETED SUICIDE	

Neurontin Indications

Indication
PAIN NOS

EXHIBIT E

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October 14, 2005

Dr. Russell Katz
Director, Neuropharmacological Drug Products
Food and Drug Administration, FDA 120
1451 Rockville Pike, Room 4037
Rockville, MD 20852

Re: FDA Neurontin Safety Analyses

Dear Dr. Katz:

Due to the continued public danger facing a substantial class of prescription drug users, I am compelled to write to you regarding the FDA's ineffective oversight related to appropriate warnings for Neurontin. Since our initial telephone conference on March 31, 2004, wherein you were informed of numerous suicides by individuals taking Neurontin, the FDA has not taken the necessary action to thoroughly examine the association between Neurontin and self-injurious behavior. The FDA's ineffective action is centered around the narrow request by the FDA for Pfizer to analyze limited clinical trials rather than all clinical trials. Not only will the narrow request result in Pfizer significantly underreporting the full extent of suicidal activity by patients taking Neurontin during clinical trials, it is contrary to the FDA's prior protocol when seeking such safety information.

On March 31, 2004, you were advised of thousands of serious psychiatric adverse events that occurred while Americans were taking Neurontin. At that time the FDA recognized a potential imminent health crisis existed, yet nothing was done to require enhanced warning labels. Due to the FDA's inaction, my firm filed a citizen's petition on May 17, 2004 with the hope that the FDA would investigate the potential for Neurontin contributing to self-injurious behavior. The FDA took six (6) months to respond and stated no decision had been reached and more time was needed to investigate. All investigations, if any, have been couched in secrecy and not open to public scrutiny while the same serious health crisis continues.

Recently my office obtained your March 16, 2005 letter to Pfizer requesting information regarding Neurontin and suicide. While an inexperienced, uninformed reader may interpret your letter as evidence that the FDA is finally taking appropriate investigatory action, my review indicates the FDA carefully framed the request to assist Pfizer in hiding the true association between Neurontin and suicide. This was accomplished by the FDA being unnecessarily overly narrow in the request.

Specifically, the FDA requested Pfizer to limit its submission only to serious psychiatric adverse events that occurred in short-term, placebo controlled trials. Therefore, Pfizer will **not** report any of the following serious adverse events which occurred in clinical trial 945-183 simply because the trial protocol did not have a placebo arm:

EVENT 1: Adverse Event: **Suicide**

Patient No. 70163, a 46-year-old Caucasian female, committed suicide while receiving 1800 mg/day of Neurontin. This event occurred on study day 15.

EVENT 2: Adverse Event: **Suicide Attempt by Drug Overdose**

Patient No. 17012, a 29-year-old Caucasian male attempted suicide by overdosing on divalproex sodium (Depakote) and Neurontin while receiving 900 mg/day of Neurontin. The event began on study day 14. The Pfizer investigator considered the event to be definitely related to Neurontin. The event was considered serious because the patient was hospitalized. Neurontin was interrupted due to this event.

EVENT 3: Adverse Event: **Psychosis Leading to Self Inflicted Chest Wound**

Patient No. 29324, a 29-year-old Hispanic female, experienced a period of psychosis and a self-inflicted stab wound to the chest while receiving 2700 mg/day of Neurontin. The psychotic episode began on study day 73 and the self-inflicted stab wound to the chest occurred on study day 76. Both events were considered to be severe in intensity with the psychosis lasting for 9 days and treatment for the stab wound for 21 days.

EVENT 4: Adverse Event: **Psychosis with Suicidal Ideation**

Patient No. 23812, a 52-year-old Hispanic female, experienced an episode of psychosis while receiving 1500 mg/day of Neurontin. The event began on study day 68. The patient presented for psychiatric admission to the Emergency Room. She was hearing voices telling her to kill herself and she feared for her life.

Clearly, the FDA's narrow request of Pfizer will result in underreporting of important suicidal adverse events that occurred during clinical trials. Why is the FDA not interested in examining the above serious adverse events?

My firm is aware of hundreds of other Neurontin clinical trials that did not have a placebo arm, many of which contain similar serious psychiatric adverse events. Pfizer, however, is not obligated to disclose them to the FDA. Is the FDA not concerned about other suicidal adverse events during clinical trials that the Pfizer investigators considered definitely related to Neurontin?

It cannot be overlooked that the narrow protocol was established by the FDA working directly with Pfizer. During your teleconferences with Pfizer on April 26 and May 6, 2004 as well as in the e-mail correspondences dated June 10, 22, 28 and July 2 and 16, the FDA acquiesced to the narrow protocol proposed by Pfizer. A clear appearance of impropriety exists when the FDA's investigative protocol was developed in conjunction with the very company the FDA is investigating, overseeing and purportedly regulating. Pfizer is aware that the number of reportable events will significantly increase if they are required to include psychiatric adverse events from all clinical trials. Pfizer successfully manipulated the FDA in a fashion that permits full compliance with the current FDA protocol while not fully disclosing the full extent of known psychiatric adverse events of patients while taking Neurontin. The FDA should be seeking ***all*** suicidal adverse events that occurred in ***all*** clinical trials of Neurontin, not just from clinical trials with a placebo controlled arm.

Seeking all adverse events from all clinical trials is the established protocol for the FDA when analyzing safety information. When the FDA was concerned that Baycol was causing too many serious adverse events, the FDA's August 2001 request from the manufacturer for safety information was far broader and performed with greater urgency than what the FDA has done with Neurontin. Specifically, the Baycol letter demanded safety data from ***all*** clinical trials the manufacturer conducted, without limitations to time or study design. Clearly, the FDA was interested in ***all*** safety events related to Baycol. Why is the FDA not interested in all suicidal events with users of Neurontin? Study design is critical in analyzing efficacy analyses. Study design is not critical when seeking to obtain the universe of all adverse events.

Additionally, why would the FDA limit Pfizer's reporting of suicidal events to no more than one day after discontinuing Neurontin? Neurontin is a drug that affects the central neurotransmitter levels. It is well known that upon initiation of Neurontin, perturbation in central neurotransmitter levels does not occur instantaneously. Similarly, upon discontinuation of Neurontin, normalization in the central neurotransmitter level does not occur instantaneously. Even with a seven (7) hour half life, there are still circulating levels of Neurontin on the first day of drug discontinuation. In patients with renal compromise, the half life is extended to as much as fifty (50) hours. More importantly, the alteration of the brain chemistry continues beyond the first day of discontinuation. Interestingly, the Baycol letter did not limit the inquiry to adverse events that occurred within one day of discontinuation.

Moreover, it appears the FDA intentionally did not request from Pfizer important materials that were sought in the Baycol request. No request for relevant safety data from the animal trials regarding Neurontin was made. No request for any current worldwide post marketing surveillance data was made. Pfizer is duty bound to obtain, compile and maintain safety data regarding Neurontin on a worldwide basis. Is the FDA not interested in knowing whether Neurontin has caused suicides or suicidal activity in other parts of the world?

Another striking difference between the FDA's request for Neurontin safety information and the FDA's request for Baycol safety information is that Pfizer is not required to provide a full translation of all approved worldwide labeling for Neurontin, as was required with Baycol. Significant differences in the warnings exist between the US label for Neurontin and other countries. For example, the British warning for Neurontin contains the following enhanced warning:

4.4 Special warnings and precautions for use

> Patients taking Neurontin can be the subject of mood and behavioral disturbances. Such reports have been noted in patients on Neurontin although a causal link has not been established.
>
> Caution is recommended in patients with a history of psychotic illness. On commencing Neurontin therapy, psychotic episodes have been reported in some patients with, and rarely without, a history of psychotic illness. Most of these events resolved when Neurontin was discontinued or the dosage was reduced.

No such enhanced warning exists on the U.S. label, therefore few US physicians know to take a history for psychotic illness before prescribing Neurontin. Is there a reason the FDA does not want to learn whether foreign regulatory agencies require stronger warnings than its own? Is there a reason the FDA does not want to warn U.S. physicians to take a history for psychotic illness before prescribing Neurontin, especially when the FDA knows 92% of the prescriptions are for off-label, unapproved uses?

The answers to these troubling questions all come to the same conclusion: the FDA wants to protect the largest pharmaceutical manufacturer in the world. Why else would you begin your March 16, 2005 letter suggesting the suicide rate for epileptics is important when analyzing the risks of Neurontin leading to suicide. Such a pretext was dismissed by the FDA when evaluating the causal association between Accutane and suicide.

Indeed, in addressing the suicide issue with Accutane, the FDA properly stated that comparisons to national averages for suicide cannot be made when analyzing the association between Accutane causing suicide. Due to the significant degree of underreporting of ingested prescription drugs taken at the time suicides are committed, no scientifically valid conclusion can be made by comparing national averages of suicides and Accutane users. The mere fact that the number of known suicides of individuals while on Accutane was lower than the expected national average did not prevent the FDA from requiring an enhanced warning of suicide related to Accutane. Therefore, your pretext that users of Neurontin are somehow predisposed to commit suicide based upon national averages is not only completely flawed, it clearly demonstrates you are inclined to conclude no association exists between Neurontin and suicidality before reviewing the requested limited, skewed data.

Regrettably, this is an example of why the American people have lost faith in the FDA's ability to protect them from unsafe drugs. While your real motivations are not known at this time, it is clear your interest is not in discovering the truth or protecting the health and safety of the American people.

Very truly yours,

FINKELSTEIN & PARTNERS, LLP

BY:
ANDREW G. FINKELSTEIN

Cc: Dr. Andrew C. von Eschenbach, Acting Commissioner FDA
Dr. Robert Temple, Office of New Product Evaluation, FDA

EXHIBIT F

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March 21, 2005

Dr. Russell Katz
Director, Neuropharmacological Drug Products
Food and Drug Administration, FDA 120
1451 Rockville Pike, Room 4037
Rockville, MD 20852

Via e-mail and regular mail

Re: NEURONTIN

Dear Dr. Katz:

Enclosed you will find two hundred fifty eight MedWatch forms, most with redacted death certificates. Each represents a suicide of an American who was on Neurontin when he or she took his or her own life. To this day, ***completed suicide*** is not found anywhere on the warning label for Neurontin.

As you know, Neurontin was recommended for approval by the Neuropharmacolgical Drug Products Division of the FDA in 1992. At that time you were Group Leader of the Division and oversaw the FDA's analysis of the clinical data supplied by Parke-Davis Pharmaceuticals, the sponsor seeking approval to sell Neurontin.

Recently, we obtained the FDA's analysis of the New Drug Application filed by Parke-Davis and found shocking information. During your evaluation of serious adverse events that occurred during original clinical trials, the risk of Neurontin causing suicide was both known and a major concern. The FDA clinical reviewer from your Division specifically stated in December, 1992:

> Serious adverse events may limit the drug's widespread usefulness. Depression, while it may not be an infrequent occurrence in the epileptic population, may become worse and require intervention or ***lead to suicide***, as it has resulted in some suicidal attempts during clinical trials. (emphasis added)

In fact, during the clinical trials Parke-Davis reported Neurontin was attributable to four people actually attempting suicide, two more having depression with suicidal ideations and twenty two participants reporting depression so severe it required pharmacologic intervention. Additionally, nineteen of the seventy eight participants who reported depression during the clinical trials had no prior history of depression.

However, since the underlying condition Neurontin helps is such a serious condition – intractable refractory seizures in adults that are not controllable with existing antiseizure medications – your Division recommended approval with "appropriate and prominent labeling for use in a specific population." Clearly, the FDA did not approve this drug with any expectation of use beyond the approved indication. Given the limited population for whom the drug was approved, and the importance of controlling intractable partial seizures, I take no issue with the ultimate approval.

In July, 1996, it came to the attention of the FDA that Parke-Davis was involved in off-label promotions of Neurontin. At that time, Lesley Frank of the FDA wrote to Parke-Davis voicing the FDA's concern:

> Parke-Davis may be promoting Neurontin for 'off-label' uses, i.e., any use beyond the FDA approved indications, in printed promotional materials, in detail or sales presentations to physicians, and through the use of company-solicited physician participation in a series of teleconferences. **These promotions of Neurontin for off-label uses included, but were not limited to, its use in chronic pain, bipolar disorders, and other psychiatric conditions.** As you are aware, Neurontin's only approved indication was for adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy. (emphasis added)

Even though the FDA knew Neurontin caused depression that may lead to suicide and that Neurontin's effects were never fully tested on people who suffered from chronic pain, bipolar disorder or other psychiatric conditions, the FDA acted with no urgency. After eleven months, Parke-Davis responded by denying all allegations and the FDA simply accepted their denial. Noteworthy, a former employee of Parke-Davis "blew the whistle" and exposed a plot to defraud physicians and healthcare providers. Through an elaborate scheme of deception, off label sales of Neurontin increased from $23 million in 1993 to $2.7 ***billion*** in 2004. By so doing, they were exposing a vulnerable population of Americans to a drug known for causing depression that leads to suicide, without proper warnings. Ultimately, the Department of Justice in Boston took notice and prosecuted only the illegal marketing and sales practices of Parke-Davis. The prosecution resulted in the company pleading guilty to multiple felonies and paying fines totaling $430 million.

More disturbing, however, is that from 1996 to today, the FDA has taken no affirmative action to require Parke-Davis to advise physicians or their patients of the risks of suicide associated with Neurontin. The FDA never issued a cease and desist letter preventing the off-label sales of Neurontin. The FDA never warned physicians of the known association between Neurontin and suicide. The FDA never required a stronger warning label be affixed on Neurontin prescriptions. The FDA's complete inaction in protecting the health and safety of United States citizens from a known serious risk of an approved drug is highly suspicious given the recent exposed relationships between pharmaceutical companies and the FDA.

On March 31, 2004, you and I had a conference call wherein we discussed the problems with Neurontin's suicidal effects. At that time you were made aware of over one hundred completed suicides and thousands of attempted suicides of Americans while on Neurontin. During that conversation you stated my firm had "the

world's largest data set addressing the question of Neurontin and suicidal behavior that exists" and were most interested in evaluating our findings. Provided I could maintain my clients' confidentiality, I agreed to provide all our raw data at the earliest possible time so as to enable the FDA to act with the swiftness this crisis required. You agreed immediate attention was necessary and advised someone from your office would contact me to coordinate the delivery of the data. Unbelievably, no one from the FDA has called or written me in the past year.

The next month, in April of 2004, my firm's Director of Adverse Event Analysis, Keith Altman, attended a conference on pharmacovigilance sponsored by the Drug Information Association. At that conference Mr. Altman had extensive conversations with Ms. Carol Krueger, a member of the Post Marketing Surveillance Division of the FDA. They specifically discussed the hundreds of known suicides related to Neurontin of which my firm was aware. Ms. Krueger agreed it was important for the FDA to send someone to my office to review the information. Yet again, no one from the FDA has called or written.

Having not heard from the FDA and receiving nearly daily notices of ongoing suicides, my firm pursued the formal administrative process. We filed a Citizens Petition on May 17, 2004, pursuant to 21 CFR 10.35 of the Federal Food, Drug and Cosmetic Act. Our petition sought one simple objective – warn the public of the potential for suicide when taking Neurontin. In our petition we asked the FDA to do two simple things: (i.) require the strongest warning on the label - a black box warning – warning of an association between Neurontin and suicide; and (ii.) require the manufacturer to disseminate "Dear Doctor" and "Dear Healthcare Professional" letters cautioning them to watch for increased depression in patients who were prescribed Neurontin.

Nearly six months later the FDA finally responded to our Citizens Petition. In a letter dated November 5, 2004, we were advised that the "FDA has been unable to reach a decision on your petition because it raises issues that require additional review and analysis by the agency." Clearly, if your agency has undertaken any analysis at all, it must have been done so without the benefit of "the world's largest data set addressing the question of Neurontin and suicidal behavior that exists" since no one from the agency has contacted my firm. Nonetheless, we do know FDA officials have had several meetings with the manufacturer regarding the issues of suicide caused by Neurontin. One can only wonder, is it the government's agenda to protect the pharmaceutical company's blockbuster drug at the expense of the safety and security of the American people?

The complete inaction by the FDA to warn an unknowing population that was relying upon the FDA to require warnings for potential adverse events from off-label usage is deplorable. The complicity by the FDA in Parke-Davis's scheme to defraud physicians and consumers is more egregious than the underlying fraud itself. The governmental body charged with the responsibility of protecting the health and safety of Americans has done absolutely nothing to prevent entirely preventable deaths. Such complicity borders on criminality.

Since our conversation of March 31, 2004, my firm has learned of seventy four additional suicides that occurred after that date. Many of these suicides likely could have been prevented had both the treating physician and unsuspecting families been armed with full knowledge of the risks of suicide that was known to both the FDA and the manufacturer.

How many more people have to die before the FDA mandates a black box warning for suicide? How many more people have to die before the FDA mandates a simple "Dear Doctor" letter advising health care providers about a known risk of Neurontin? The administrative process has failed to date. If this failure is in anyway due

to my error kindly advise so I can cure it immediately. If I do not hear from you by April 8, 2005, I will presume your inaction is not based in anyway through a deficiency on my part and I will act accordingly.

I sincerely hope to hear from you.

Very truly yours,

FINKELSTEIN & PARTNERS, LLP

BY: ANDREW G. FINKELSTEIN

AGF/jam
Enclosure

Cc: Dr. Lester Crawford, Acting Commissioner FDA
Dr. Robert Temple, Office of New Product Evaluation, FDA
Hon. Charles Schumer
Hon. Hillary Rodham Clinton
Hon. Maurice D. Hinchey
Hon. Charles Grassley
Hon. John Dingell
Hon. Henry Waxman
Hon. Richard Stearns, USDJ

EXHIBIT G

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

In re "AGENT ORANGE" PRODUCT LIABILITY LITIGATION	MDL No. 381
JOE ISAACSON and PHILLIS LISA ISAACSON, Plaintiffs, -against- DOW CHEMICAL COMPANY, et al., Defendants.	MEMORANDUM & ORDER (REMOVAL) 98-CV-6383 (JBW)

APPEARANCES:

For Plaintiffs Joe Isaacson; and Phillis Lisa Isaacson:

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Jack B. Weinstein, Senior United States District Judge:

Table of Contents

I. Introduction

Plaintiff, Joe Isaacson, is a Vietnam veteran. He claims injuries from exposure to Agent Orange during his service in Vietnam from 1968 to1969. Defendants manufactured and sold Agent Orange to the United States for use by the military as a defoliant in Vietnam. This case has been remanded to determine whether there is federal jurisdiction. *See Stephenson v. Dow Chemical Co.*, 346 F.3d 19 (2d Cir. 2003).

Originally filed in New Jersey state court, the complaint alleged claims under state law only. Defendants removed the case to federal court, asserting a variety of jurisdictional grounds: 28 U.S.C. §§ 1651 (All Writs Act), 1442 (acting under federal officer), 1332 (diversity), and 1331 (federal question). The District Court for the District of New Jersey approved removal based on the All Writs Act, 28 U.S.C. § 1651. The case was then transferred to this court by the Multidistrict Panel. MDL 381. The Court of Appeals for the Second Circuit approved removal solely on the basis of the All Writs Act. *Stephenson v. Dow Chemical Co.*, 273 F.3d 249 (2d Cir. 2001).

The Supreme Court remanded in light of its holding in *Syngenta Crop Protection, Inc. v. Henson*, 537 U.S. 28 (2002), indicating that the All Writs Act alone would not support removal. *Dow Chemical Co. v. Stephenson*, 123 S. Ct. 2161 (2003) (per curiam). On remand from the Supreme Court, the Second Circuit determined that jurisdiction could not be grounded in the All Writs Act and remanded the case to this court to determine if there is an alternate ground supporting federal jurisdiction. *Stephenson v. Dow Chemical Co.*, 346 F.3d 19 (2d Cir. 2003).

Pending is plaintiff's motion to remand the case to state court on the ground that there is no basis for federal jurisdiction. Defendants contend that the case is removable.

It would not be removable on diversity grounds since diversity of parties is lacking. Nor would it be removable on the ground that plaintiffs have stated a federal cause of action since the Court of Appeals by a split decision disagreed with this court that federal substantive law was the predicate for Agent Orange claims. *See In re "Agent Orange" Prod. Liab. Litig.*, 635 F.2d 987 (2d Cir. 1980), *cert. denied*, 454 U.S. 1128 (1981). The only other basis is the federal officer removal statute. 28 U.S.C. § 1442(a)(1).

For reasons indicated below, the motion to remand is denied. Federal jurisdiction is properly asserted under the federal officer removal statute. A prior decision of this court reached a contrary conclusion in an Agent Orange case. *See Ryan v. Dow Chemical Co.*, 781 F. Supp. 934 (E.D.N.Y. 1992). The *Ryan* decision is no longer persuasive. As the Court of Appeals for the Fifth Circuit pointed out in rejecting *Ryan's* conclusion, this court recognized its decision on the point as "close" and "uncertain." *Winters v. Diamond Shamrock Chemical Co.*, 149 F.3d 387, 392 (5th Cir. 1998). *Ryan* was "not legally capable of appellate review." *Id. Winters*, a persuasive appellate decision, on facts almost identical to those in *Ryan*, held the federal officer removal statute applicable to the defendants in the instant case. *Id.* at 401; *see also Miller v. Dow Chemical Co.*, 275 F.3d 414, 417 (5th Cir. 2001) (same).

II. Facts

The facts supporting removal of the case on the basis of the federal officer removal statute are set forth in extensive contractual and other documents. *See In re "Agent Orange" Products Liability Litigation*, Judgment and Order of Dismissal, --- F. Supp.2d --- (E.D.N.Y. Feb. 9, 2004) ("*Judgment in Agent Orange III*"). *Judgment in Agent Orange III* contains a description of the relevant facts. It is deemed incorporated in this memorandum and order.

III. Law

A. General Rule

The federal officer removal statute allows executive branch officials and persons acting under them to remove to a federal court civil and criminal actions brought against them in a state court for their official acts. The relevant portion of Section 1442(a)(1) of Title 28 of the United States Code reads:

> (a) A civil action or criminal prosecution commenced in a State court against any of the following may be removed by them to the district court of the United States for the district and division embracing the place wherein it is pending:
>
> (1) The United States or any agency thereof or any officer (or any person acting under that officer) of the United States or of any agency thereof, sued in an official or individual capacity for any act under color of such office. . . .

The statute has its origins in Congress's response to the New England states' opposition to the War of 1812. *Willingham v. Morgan*, 395 U.S. 402, 405 (1969). Its reach was extended through the years, taking its current form in the enactment of the Judicial Code of 1948. *Mesa v. California*, 489 U.S. 121, 126 (1989).

Section 1442(a)(1) is designed to prevent state courts from interfering with the implementation of federal law. It does so by allowing those whose activities on behalf of the federal government may be inhibited by state court actions to remove the cases to a presumably less biased federal forum. If one defendant may remove under section 1442, then the entire case is removed to federal court even if some defendants could not have removed the case under the statute. *See, e.g., Falls Riverway Realty v. City of Niagara Falls*, 754 F.2d 49, 52 (2d Cir. 1985) (noting that one government defendant removed the "entire case"); 3 Moore's Federal Practice ¶ 1442.2. Subject matter jurisdiction is conferred over properly removed actions. *Niagara Mohawk Power Corp. v. Bankers Trust Co.*, 791 F.2d 242, 244 (2d Cir. 1986).

In general, lawsuits may be removed from state court to federal court only if a federal district court would have had original jurisdiction over the suit–the "well pleaded complaint rule." *Caterpillar, Inc. v. Williams*, 482 U.S. 386, 392 (1987). The federal officer removal statute expands the scope of federal jurisdiction; an action may be properly removed if it satisfies

three elements. *See, e.g., Mesa*, 489 U.S. at 136 ("The removal statute itself merely serves to overcome the 'well-pleaded complaint' rule which would otherwise preclude removal even if a federal defense were alleged.").

First, a defendant must demonstrate that it is a "person" within the meaning of the statute. Second, the defendant must establish that the suit is "for any act under color of [federal] office," i.e., there is a "causal connection between the charged conduct and asserted official authority." *Willingham*, 395 U.S. at 409 (citations omitted). Causation exists if the predicate acts of the state suit were undertaken while a person was acting as or under a federal officer, and the acts were under color of the relevant federal office. *Ryan*, 781 F. Supp at 939. Third, defendants must raise a colorable claim to a federal law defense. *Mesa*, 489 U.S. at 131-38.

Defendants claim to have been persons "acting under" federal officers within the meaning of section 1442(a)(1) when they manufactured and delivered to the Department of Defense for use in war the herbicides that plaintiff alleges injured him. The primary question in the instant case is whether defendants' conduct allegedly giving rise to plaintiffs' state law claims constituted acts under a federal officer within the meaning of section 1442(a)(1).

B. Elements of Section 1442(a)(1)

1. Definition of Person

"[U]nless the context indicates otherwise . . . the words 'person' and 'whoever' include corporations, companies, . . . , and joint stock companies, as well as individuals. . . ." 1 U.S.C. § 1. The Supreme Court has not ruled on whether corporations can be considered persons under the federal officer removal statute. In its most recent explication of the meaning of "person," the Court held that a federal agency was not a person under the statute. *Int'l Primate Protection*

League v. Adm'r of Tulane Educ. Fund, 500 U.S. 72 (1991). Responding to the *International Primate* decision, Congress amended the statute to allow for removal by federal agencies. Federal Courts Improvement Act of 1996, Pub. L. 104-317, 110 Stat. 3847, 3850; *see also Nebraska ex. rel Dept. of Soc. Servs. v. Bentson*, 146 F.3d 676, 678 (9th Cir. 1998); *Dalrymple v. Grand River Dam Auth.*, 145 F.3d 1180, 1184 n.6 (10th Cir. 1998) (deeming the amendment a legislative reversal of *International Primate*).

Congress's amendment of the statute to emphasizes its broad scope supports the conclusion that "person" encompasses more than mere individuals. Protection of federal government operations in today's organizational climate where so much of our economy and government outsourcing depends upon corporations requires this result. Under section 1442(a)(1) a "person" includes a corporation. *See Winters v. Diamond Shamrock Chemical Co.*, 149 F.3d 387 (5th Cir. 1998); *Thompson v. Comm. Ins.* Co., 1999 U.S. Dist. LEXIS 21725 (S.D. Ohio 1999); *Arness v. Boeing N. Am., Inc.*, 997 F. Supp. 1268, 1272 (C.D. Cal. 1998); *Ruffin v. Armco Steel Corp.*, 959 F. Supp. 770, 773 (S.D. Tex. 1997); *Good v. Armstrong World Indus.*, 914 F. Supp. 1125, 1127-1128 (E.D. Pa. 1996); *Fung v. Abex Corp.*, 816 F. Supp. 569, 572 (N.D. Cal. 1992); *Akin v. Big Three Indus., Inc.*, 851 F. Supp. 819, 822-23 (E.D. Tex. 1994); *Ryan*, 781 F. Supp. at 946-47.

2. Acting Under Color of Federal Office

The "color of office" requirement should not be frustrated by a "narrow" construction. Courts interpret the rule broadly to achieve the protective purpose of the statute. *Willingham*, 395 U.S. at 407. This element requires a causal nexus between the defendant's actions under federal office and plaintiff's state court claims. *Id.* at 409; *Winters*, 149 F.3d at 398. A

substantial degree of direct and detailed federal control over the defendant's work is required. *Winters*, 149 F.3d at 398; *Arness*, 997 F. Supp. at 1273.

Cases applying section 1442(a)(1) involving defense contractors support the defense's contentions in the present litigation. In *Winters*, for example, plaintiffs sued Agent Orange manufacturers under almost identical facts. *See Judgment in Agent Orange III.* Defendants sought removal. The court determined that it was sufficient that the government specified "the composition of Agent Orange so as to supply the causal nexus between the federal officer's directions and the plaintiff's claims." *Winters*, 149 F.3d at 398. Central to the court's holding was a finding identical to that in the instant case-- "that the government maintained strict control over the development and subsequent production of Agent Orange." *Id.* at 399.

The Fifth Circuit approved removal based on the federal officer statute in a subsequent Agent Orange case. *Miller v. Dow Chemical Co.*, 275 F.3d 414, 417 (5th Cir. 2001). By contrast– unlike the case at bar– federal control was almost nonexistent in *Arness v. Boeing North American*. The plaintiffs had sued Boeing based on Boeing's disposal of a toxic substance used to "flush rocket engine hardware." 997 F. Supp. at 1273. Government specifications required Boeing to clean the engines with a toxic substance, but did not specify how Boeing was to dispose of the cleanser. The court found that a federal officer did not direct or control Boeing's disposal of the toxin, and, thus, there was no connection between the plaintiffs' claims and Boeing's actions at the direction of a federal officer. *Id.* at 1275.

Akin v. Big Three Indus., Inc. illustrates a properly removable case. 851 F. Supp. 819 (E.D. Tex. 1994), *removal aff'd by Akin v. Ashland Chemical Co.*, 156 F.3d 1030 (10th Cir. 1998). A corporate manufacturer of jet engines was involved in a toxic tort case arising out of

chemical exposure at an Air Force base. The defendants produced the jet engines in accordance with government specifications. Repairing the engines involved a grinding process, which necessarily gave rise to the emission of objectionable chemicals. The court held that the "acting under" requirement is satisfied when "a government contractor builds a product pursuant to Air Force specifications and is later sued because compliance with those specifications allegedly causes personal injuries." *Id.* at 823-24. Likewise, in *Crocker v. Borden*, the claim was based on exposure to asbestos while the plaintiffs were shipyard employees. 852 F. Supp. 1322 (E.D. La. 1994). Defendants utilized asbestos as insulation in marine turbines. The marine turbines were manufactured pursuant to government specifications for the Navy. The court held that this government control established the necessary "causal nexus." *Id.* at 1327. *See also, e.g., Reed v. Fina Oil & Chemical Co.*, 995 F. Supp. 705 (E.D. Tex. 1998) (government dictated processes through which the victim initially came into contact with chemicals allegedly causing disease; government controlled specifications of chemicals); *Pack v. AC and S, Inc.*, 838 F. Supp. 1099 (D. Md. 1993) (government had extensive control over manufacture of turbines, even specifying type of asbestos cloth).

The "causal nexus" is also satisfied when there is evidence of intimate government involvement in the design decisions causally related to the alleged tort. As stated in *Arness*, defendants must show that the government directed the actions on which the plaintiffs based their claims. 997 F. Supp. at 1275. By contrast, in *Good v. Armstrong World Industries, Inc.*, plaintiffs sued for injuries related to asbestos exposure. 914 F. Supp. 1125 (E.D. Pa. 1996). The court found that the Navy was involved in the design and manufacture of the turbines, but that it did not specify the use of asbestos. Acting under the general direction of the Navy "is not the

same as acting under the direct and detailed control of a federal officer." *Id.* at 1129. *But cf. Crocker v. Borden*, 852 F. Supp. 1322 (1994) (opposite holding under similar facts). Similarly, in *Anderson v. Avondale Indus., Inc.*, defendant's attempt at removal was defeated by an inability to prove "intimate government oversight or involvement in the design or production of [a lagging adhesive]." 1994 U.S. Dist. LEXIS 17598, *10 (E.D. La. 1994).

3. Colorable Claim to a Federal Law Defense

Removal "must be predicated on the allegation of a colorable federal defense." *Mesa*, 489 U.S. at 129. In deciding whether a defendant has such a defense, courts reject a "narrow, grudging interpretation;" they do not require that the defense is likely to be successful on the merits. *Jefferson County v. Acker*, 527 U.S. 423, 431 (1999) (citation omitted).

Support of removal may be predicated on the federal government contractor defense. *See, e.g., Judgment in Agent Orange III*; *Winters*, 149 F.3d at 401; *Miller*, 275 F.3d at 418; *Guillory v. Ree's Contract Serv. Inc.*, 872 F. Supp. 344, 346 (S.D. Miss. 1994) (denying removal on other grounds); *Crocker*, 852 F. Supp. at 1327; *Akin*, 851 F. Supp. at 823; *AC & S, Inc.*, 838 F. Supp. at 1103; *Fung v. Abex Corp.*, 816 F. Supp. 569, 573 (N.D. Cal. 1992). *But see Freiberg v. Swinerton & Walberg Prop. Servs.*, 245 F. Supp. 2d 1144, 1151 n.5 (D. Colo. 2002) (questioning "whether the government contractor 'defense' asserted by Swinerton here is the type of federal interest or immunity for which § 1442(a)(1) was intended to provide an exclusively federal forum").

IV. Application of Law to Facts

Defendants corporations are persons under Section 1442(a)(1).

The government designed, controlled, and supervised the production of Agent Orange as

a product vital to the prosecution of the war in Vietnam. *See Judgment in Agent Orange III.* Formal military specifications and requirements for Agent Orange were prepared and promulgated by the government. After the testing of many different herbicides, the military concluded that a mixture of the butyl esters of 2,4-D and 2,4,5-T was most effective for military defoliation purposes. Federal officers determined through government specifications that the "formulation" for Agent Orange would be a 50/50 mix of the n-butyl esters of 2,4-D and 2,4,5-T. The government determined that "extremely high dose rates" of these undiluted herbicides were required for effective military use.

Commencing in 1961, defendants produced and delivered Agent Orange to the United States pursuant to numerous contracts entered into with the Defense General Supply Center, the Defense Fuel Supply Center, the United States Army or the United States Air Force. The contracts set forth or incorporated by reference detailed specifications for the herbicide. Those specifications were promulgated by the government. A government directive issued pursuant to Section 101 of the Defense Production Act of 1950 commandeered the United States industry's entire capacity to manufacture 2,4,5-T, ordering defendants to accelerate the delivery of Agent Orange. *See, e.g., Hercules, Inc. v. United States*, 516 U.S. 417, 419 (1996) ("The military prescribed the formula and detailed specifications for manufacture."). The government also strictly and precisely defined the markings that were to be placed on drums of Agent Orange supplied by defendants, prohibiting the placement of warnings.

The government was aware of the dioxin in Agent Orange. It knew more about its dangers than defendants. The herbicidal properties of 2,4-D and 2,4,5-T were explored in research conducted by the United States military during World War II. In the 1950s, scientists at

the Army Chemical Corps Chemical Warfare Laboratories located at Edgewood Arsenal, Maryland learned of dioxin as a toxic by-product in the manufacture of 2,4,5-T. The President's Science Advisory Committee ("PSAC"), an organization within the White House, was briefed by the military on the Vietnam defoliation program in 1963 and recognized dioxin as an element in Agent Orange.

As the Court of Appeals for the Fifth Circuit concluded in *Winters* and *Miller*, the Agent Orange supplied to the government was not a ready-to-order, preexisting or off-the-shelf chemical mixture. The court noted in *Winters*:

> Although the defendants had produced 2,4-D and 2,4,5-T for commercial use before government involvement, their commercial formulations were never composed of a mixture of 100% pure 2,4-D/ 2,4,5-T, which the government required for the most part (98% for 2,4-D and 99% for 2,4,5-T) in its contracts with the defendants. Instead, the defendants had always included a substantial percentage of inert ingredients to dilute the two active ingredients and required further dilution before commercial application. In contrast, the government's specifications for Agent Orange included use of the two active chemicals in unprecedented quantities for the specific purpose of stripping certain areas of Vietnam of their vegetation. To quickly achieve this goal, the government dictated that Agent Orange contain only the active ingredients 2,4-D and 2,4,5-T and it applied the product in Vietnam without dilution.

Winters, 149 F.3d at 399; *see also Miller*, 275 F.3d at 419.

This case is distinguishable from *Arness v. Boeing North American*. As already noted, in *Arness*, defendants were sued based on the effect of their method of disposal of a toxic by-product. 997 F. Supp. At 1273. The government had not specified the manner in which the toxic by-product would be disposed of. Here, the government ordered specifications that differed from defendants' commercial applications. In addition, the method of warning and application was

completely in the government's hands.

The government's full knowledge of the dioxin "problem" inherent in the production of Agent Orange is evidence that the federal officials maintained control over the acts on which the litigation is based. *See Miller*, 275 F.3d 418; *Winters*, 149 F.3d at 400. *See also, e.g., Akin v. Big Three Indus., Inc.*, 851 F. Supp. 918 (E.D. Tex. 1994); *Pack v. AC and S, Inc.*, 838 F. Supp. 1099 (D. Md. 1993); *Fung v. Abex Corp.*, 816 F. Supp. 569 (N.D. Cal. 1992); *Judgment in Agent Orange III.*

The final element of removal under Section 1442(a)(1) is whether defendants have established a "colorable federal [law] defense." *Mesa v. California* 489 U.S. 121, 129 (1989). Although the Supreme Court has stated that "one of the most important reasons for removal is to have the validity of the defense of official immunity tried in a federal court," *Willingham*, 395 U.S. at 407, the Court did not limit the scope of federal law defenses in removal cases to immunities. The government contractor defense is a colorable federal law defense in much the same way self-defense is a colorable state law defense to civil assault charges. In an assault case, the defendant may claim: "He made me do it;" here a defendant may properly assert, "'The Government made me do it.'" *In re Joint Eastern and Southern Dist. New York Asbestos Litigation (Grispo v. Eagle-Picher Industries, Inc.)*, 897 F.2d 626, 632 (2d Cir. 1990).

An element of the government contractor defense is that the contractor must inform the government of any dangerous consequences known to it but not to the government. This requirement is satisfied in the present case. *See Judgment Agent Orange III*; *see also, e.g., Winters*, 149 F.3d at 401.

The defendants have satisfied all elements for removal to federal court based on section

1442(a)(1) of Title 28 of the United States Code. As "persons" acting under a federal officer, in the Agent Orange litigation, defendants were proxies for the government.

V. Policy Considerations Supporting Removal

The military contractor defense is based upon substantive policy considerations as well as pragmatic procedural factors in controlling litigation. The government contractor defense, provides substantive protection for the armed forces and its suppliers. *See Boyle v. United Technologies Corp.*, 487 U.S. 500, 512 (1988). Section 1442(a)(1) provides procedural protection. Failure to apply the federal officer removal statute would allow into the back door of state litigation what the government contractor defense barred at the front door.

If cases such as those in this present wave of Agent Orange claims were scattered throughout state courts manufacturers would have to seriously consider whether they would serve as procurement agents to the federal government. Since the advent of the Agent Orange litigation in 1979, mass tort law has become more hazardous for defendants. While on balance state tort law does more good than harm, its vagaries and hazards would provide a significant deterrent to necessary military procurement.

Because government contractor cases are freighted with factual findings, *Boyle*, while laying down a substantive rule, may be readily circumvented by state courts unsympathetic to the defendants. Central to "Congress' concern [was] local hostility to federal authority." *Mesa*, 489 U.S. at 140 (BRENNAN, J., concurring). "Congress has decided that federal officers, and indeed, the Federal Government itself, require the protection of a federal forum. This policy should not be frustrated by a narrow, grudging interpretation of § 1442(a)(1)." *Willingham*, 395 U.S. at 407. While there are theoretical protections in the Supreme Court's power to directly

review a state court's decision prejudicial to the federal government and its contractors, very few cases can be reviewed by this route. *Cf.* Kermit Roosevelt III, *Light from Dead Stars: The Procedural Adequate and Independent State Ground Reconsidered*, 103 Colum. L. Rev. 1888, 1918 (2003) (noting that in habeas corpus cases that "the task of error-correction, once the province of the Supreme Court on direct review, has been farmed out to the district courts").

VI. Conclusion

Plaintiffs' motion to remand is denied. No costs or disbursements.

SO ORDERED.

Jack B. Weinstein

Dated February 9, 2004
Brooklyn, New York